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# Pesticide Registration Standard
# 2,3-dichloro - 1,4-naphthoquinone (Dichlone)

(U.S.) Environmental Protection Agency
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Agency

Office of
Pesticides and Toxic Substances
Washington DC 20460

January 1981

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EPA

# 2, 3-dichloro - 1, 4-naphthoquinone (Dichlone)

## Pesticide Registration Standard

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This document presents the registration standard for Dichlone® and summarizes the requirements for registering or re-registering a pesticide containing that active ingredient. Requirements for submitting scientific data, evaluating hazards associated with the chemical, and meeting requirements for registration are covered. The document also contains a bibliography citing all the studies reviewed by EPA in arriving at the positions and conclusions stated in the standard.

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# DICHLONE

## Pesticide Registration Standard

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# CHAPTER I

## HOW TO REGISTER UNDER A REGISTRATION STANDARD

Organization of the Standard
Purpose of the Standard
Requirement to Re-register Under the Standard
"Product Specific" Data and "Generic" Data
Data Compensation Requirements under FIFRA 3(c)(1)(D)
Obtaining Data to Fill " Data Gaps"; FIFRA 3(c)(2)(B)
Amendments to the Standard

### Organization of the Standard

This first chapter explains the purpose of a Registration Standard and summarizes the legal principles involved in registering or re-registering under a Standard. The second chapter sets forth the requirements that must be met to obtain or retain registration for products covered by this particular Registration Standard. In the remaining chapters, the Agency reviews the available data by scientific discipline, discusses the Agency's concerns with the identified potential hazards, and logically develops the conditions and requirements that would reduce those hazards to acceptable levels.

### Purpose of the Standard

Section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) provides that "no person in any State may distribute, sell, offer for sale, hold for sale, ship, deliver for shipment, or receive (and having so received) deliver or offer to deliver, to any person any pesticide which is not registered with the Administrator [of EPA]." To approve the registration of a pesticide, the Administrator must find, pursuant to Section 3(c)(5) that:

"(A) its composition is such as to warrant the proposed claims for it;
(B) its labeling and other material required to be submitted comply with the requirements of this Act;
(C) it will perform its intended function without unreasonable adverse effects on the environment; and
(D) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment."

In making these findings, the Agency reviews a wide range of data which registrants are required to submit, and assesses the risks and benefits associated with the use of the proposed pesticide. But the established approach to making these findings has been found to be defective on two counts:

First, EPA and its predecessor agency, the United States Department of Agriculture (USDA), routinely reviewed registration applications on a "product by product" basis, evaluating each product-specific application somewhat independently. In the review of products containing similar components, there was little opportunity for a retrospective review of the full range of pertinent data available in Agency files and in the public literature. Thus the "product by product" approach was often inefficient and sometimes resulted in inconsistent or incomplete regulatory judgments.

Second, over the years, as a result of inevitable and continuing advances in scientific knowledge, methodology, and policy, the data base for many pesticides came to be considered inadequate by current scientific and regulatory standards. Given the long history of pesticide regulation in several agencies, it is even likely that materials may have been lost from the data files. When EPA issued new requirements for registration in 1975 (40 CFR 162) and proposed new guidelines for hazard testing in 1978 (43 FR 29686, July 10, 1978 and 43 FR 37336, August 2, 1978), many products that had already been registered for years were being sold and used without the same assurances of human and environmental safety as was being required for new products. Because of this inconsistency, Congress directed EPA to re-register all previously registered products, so as to bring their registrations and their data bases into compliance with current requirements, [See FIFRA Section 3(g)].

Facing the enormous job of re-reviewing and calling-in new data for the approximately 35,000 current registrations, and realizing the inefficiencies of the "product by product" approach, the Agency decided that a new, more effective method of review was needed.

A new review procedure has been developed. Under it, EPA publishes documents called Registration Standards, each of which discusses a particular pesticide active ingredient. Each Registration Standard summarizes all the data available to the Agency on a particular active ingredient and its current uses, and sets forth the Agency's comprehensive position on the conditions and requirements for registration of all existing and future products which contain that active ingredient. These conditions and requirements, all of which must be met to obtain or retain full registration or reregistration under Section 3(c)(5) of FIFRA, include the submission of needed scientific data which the Agency does not now have, compliance with standards of toxicity, composition, labeling, and packaging, and satisfaction of the data compensation provisions of FIFRA Section 3(c)(1)(D).

The Standard will also serve as a tool for product classification. As part of the registration of a pesticide product, EPA may classify each product for "general use" or "restricted use" [FIFRA Section 3(d)]. A pesticide is classified for "restricted use" when some special regulatory restriction is needed to ensure against unreasonable adverse effects to man or the environment. Many such risks of unreasonable adverse effects can be lessened if expressly-designed label precautions are strictly followed. Thus the special regulatory restriction for a "restricted use" pesticide is usually a requirement that it be applied only by, or under the supervision of, an applicator who has been certified by the State or Federal government as being competent to use pesticide safely, responsibly, and in accordance with label directions. A restricted-use pesticide can have other regulatory restrictions [40 CFR 162.11(c)(5)] instead of, or in addition to, the certified applicator requirement. These other regulatory restrictions may include such actions as seasonal or regional limitations on use, or a requirement for the monitoring of residue levels after use. A pesticide classified for "general use," or not classified at all, is available for use by any individual who is in compliance with State or local regulations. The Registration Standard review compares information about potential adverse effects of specific uses of the pesticide with risk criteria listed in 40 CFR 162.11(c), and thereby determines whether a product needs to be classified for "restricted use." If the Standard does classify a pesticide for "restricted use," this determination is stated in the second chapter.

## Requirement to Reregister Under the Standard

FIFRA Section 3(g), as amended in 1978, directs EPA to reregister all currently registered products as expeditiously as possible. Congress also agreed that reregistration should be accomplished by the use of Registration Standards.

Each registrant of a currently registered product to which this Standard applies, and who wishes to continue to sell or distribute his product in commerce, must apply for reregistration. His application must contain proposed labeling that complies with this Standard.

EPA will issue a notice of intent to cancel the registration of any currently registered product to which this Standard applies if the registrant fails to comply with the procedures for reregistration set forth in the Guidance Package which accompanies this Standard.

## "Product Specific" Data and "Generic" Data

In the course of developing this Standard, EPA has determined the types of data needed for evaluation of the properties and effects of products to which the Standard applies, in the disciplinary areas of Product Chemistry, Environmental Fate, Toxicology, Residue Chemistry, and Ecological Effects. These determinations are based primarily on the data Guidelines proposed in 43 FR 29696, July 10, 1978; 43 FR 37336, August 22, 1978; and 45 FR 72948, November 3, 1980, as applied to the use patterns of the products to which this Standard applies. Where it appeared that data from a normally applicable Guidelines requirement was actually unnecessary to evaluate these products, the Standard indicates that the requirement has been waived. On the other hand, in some cases studies not required by the Guidelines may be needed because of the particular composition or use pattern of products the Standard covers; if so, the Standard explains the Agency's reasoning. Data guidelines have not yet been proposed for the Residue Chemistry discipline, but the requirements for such data have been in effect for some time and are, the Agency believes, relatively familiar to registrants. Data which we have found are needed to evaluate the registrability of some products covered by the Standard may not be needed for the evaluation of other products, depending upon the composition, formulation type, and intended uses of the product in question. The Standard states which data requirements apply to which product categories. (See the second chapter.) The various kinds of data normally required for registration of a pesticide product can be divided into two basic groups:

(A) data that are product specific , i.e. data that relates only to the properties or effects of a product with a particular composition (or a group of products with closely similar composition); and

(B) generic data that pertains to the properties or effects of a particular ingredient, and thus is relevant to an evaluation of the risks and benefits of all products containing that ingredient (or all such products having a certain use pattern), regardless of any such product's unique composition.

The Agency requires certain "product specific" data for each product to characterize the product's particular composition and physical/chemical properties (Product Chemistry), and to characterize the product's acute toxicity (which is a function of its total composition). The applicant for registration or reregistration of any product, whether it is a manufacturing-use or end-use product, and without regard to its intended use pattern, must submit or cite enough of this kind of data to allow EPA to evaluate the product. For such purposes, "product specific" data on any product other than the applicant's is irrelevant, unless the other product is closely similar in composition to the applicant's. (Where it has been found practicable to group similar products for purposes of evaluating, with a single set of tests, all products in the group, the Standard so indicates.) "Product specific" data on the efficacy of particular end-use products is also required where the exact formulation may affect efficacy and where failure of efficacy could cause public health problems.

All other data needed to evaluate pesticide products concerns the properties or effects of a particular ingredient of products (normally a pesticidally active ingredient, but in some cases a pesticidally inactive, or "inert," ingredient). Some data in this "generic" category are required to evaluate the properties and effects of all products containing that ingredient [e.g., the acute LD-50 of the active ingredient in its technical or purer grade; see proposed 40 CFR 163.81-1(a), 43 FR 37355].

Other "generic" data are required to evaluate all products which both contain a particular ingredient and are intended for certain uses (see, e.g., proposed 40 CFR 163.82-1, 43 FR 37363, which requires subchronic oral testing of the active ingredient with respect to certain use patterns only). Where a particular data requirement is use-pattern dependent, it will apply to each end-use product which is to be labeled for that use pattern (except where such end-use product is formulated from a registered manufacturing-use product permitting such formulations) and to each manufacturing-use product with labeling that allows it to be used to make end-use products with that use pattern. Thus, for example, a subchronic oral dosing study is needed to evaluate the safety of any manufacturing-use product that legally could be used to make an end-use, food-crop pesticide. But if an end-use product's label specified it was for use only in ways that involved no food/feed exposure and no repeated human exposure, the subchronic oral dosing study would not be required to evaluate the product's safety; and if a manufacturing-use product's label states that the product is for use only in making end-use products not involving food/feed use or repeated human exposure, that subchronic oral study would not be relevant to the evaluation of the manufacturing-use product either.

If a registrant of a currently registered manufacturing-use or end-use product wishes to avoid the costs of data compensation [under FIFRA Section 3(c)(1)(D)] or data generation [under Section 3(c)(2)(B)] for "generic" data that is required only with respect to some use patterns, he may elect to delete those use patterns from his labeling at the time he reregisters his product. An applicant for registration of a new product under this Standard may similarly by request approval for only certain use patterns.

## Data Compensation Requirements under FIFRA 3(c)(1)(D)

Under FIFRA Section 3(c)(1)(D), an applicant for registration, reregistration, or amended registration must offer to pay compensation for certain existing data the Agency has used in developing the Registration Standard. The data for which compensation must be offered is all data which aredescribed by all the following criteria:

(1) the data were first submitted to EPA (or to its predecessor agencies, USDA or FDA), on or after January 1, 1970;
(2) the data were submitted to EPA (or USDA or FDA) by some other applicant or registant in support of an application for an experimental use permit, an amendment adding a new use to a registration, or for registration, or to support or maintain in effect an existing registration;
(3) they are the kind of data which are relevant to the Agency's decision to register or reregister the applicant's product under the Registration Standard, taking into account the applicant's product's composition and intended use pattern(s);
(4) the Agency has found the data to be valid and usable in reaching regulatory conclusions; and
(5) they are not data for which the applicant has been exempted by FIFRA Section 3(c)(2)(D) from the duty to offer to pay compensation. (This exemption applies to the "generic" data concerning the safety of an active ingredient of the applicant's product, not to "product specific" data. The exemption is available only to applicants whose product is labeled for end-uses for which the active ingredient in question is present in the applicant's product because of his use of another registered product containing that active ingredient which he purchases from another producer.)

An applicant for reregistration of an already registered product under this Standard, or for registration of a new product under this Standard, accordingly must determine which of the data used by EPA in developing the Standard must be the subject of an offer to pay compensation, and must submit with his application the appropriate statements evidencing his compliance with FIFRA Section 3(c)(1)(D).

An applicant would never be required to offer to pay for "product specific" data submitted by another firm. In many, if not in most cases, data which is specific to another firm's product will not suffice to allow EPA to evaluate the applicant's product, that is, will not be useful to the Agency in determining whether the applicant's product is registrable. There may be cases, however, where because of close similarities between the composition of two or more products, another firm's data may suffice to allow EPA to evaluate some or all of the "product specific" aspects of the applicant's product. In such a case, the applicant may choose to cite that data instead of submitting data from tests on his own product, and if he chooses that option, he would have to comply with the offer-to-pay requirements of Section 3(C)(1)(D) for that data.

Each applicant for registration or reregistration of a manufacturing-use product, and each applicant for registration or reregistration of an end-use product, who is not exempted by FIFRA Section 3(c)(2)(D), must comply with the Section 3(c)(1)(D) requirements with respect to each item of "generic" data that relates to his product's intended uses.

A detailed description of the procedures an applicant must follow in applying for reregistration (or new registration) under this Standard is found in the Guidance Package for this Standard.

## Obtaining Data to Fill "Data Gaps"; FIFRA 3(c)(2)(B)

Some of the kinds of data EPA needs for its evaluation of the properties and effects of products to which this Standard applies have never been submitted to the Agency (or, if submitted, have been found to have deficiencies rendering them inadequate for making registrability decisions) and have not been located in the published literature search that EPA conducted as part of preparing this Standard. Such instances of missing but required data are referred to in the Standard as "data gaps".

FIFRA Section 3(c)(2)(B), added to FIFRA by the Congress in 1978, authorizes EPA to require registrants to whom a data requirement applies to generate (or otherwise produce) data to fill such "gaps" and submit those data to EPA. EPA must allow a reasonably sufficient period for this to be accomplished. If a registrant fails to take appropriate and timely steps to fill the data gaps identified by a section 3(c)(2)(B) order, his product's registration may be suspended until the data is submitted. A mechanism is provided whereby two or more registrants may agree to share in the costs of producing data for which they are both responsible.

The Standard lists, in its summary second chapter, the "generic" data gaps and notes the classes of products to which these data gaps pertain. The Standard also points out that to be registrable under the Standard, a product must be supported by certain required "product specific" data. In some cases, the Agency may possess sufficient "product specific" data on one currently registered product, but may lack such data on another. Only those Standards which apply to a very small number of currently registered products will attempt to state definitively the " product specific" data gaps on a "product by product" basis. (Although the Standard will in some cases note which data that EPA does possess would suffice to satisfy certain "product specific" data requirements for a category of products with closely similar composition characteristics.)

As part of the process of reregistering currently registered products, EPA will issue Section 3(c)(2)(B) directives requiring the registrants to take appropriate steps to fill all identified data gaps -- whether the data in question are "product specific" or "generic" -- in accordance with a schedule.

Persons who wish to obtain registrations for new products under this Standard will be required to submit (or cite) sufficient "product specific" data before their applications are approved. Upon registration, they will be required under Section 3(c)(2)(B) to take appropriate steps to submit data needed to fill "generic" data gaps. (We expect they will respond to this requirement by entering into cost-sharing agreements with other registrants who previously have been told they must furnish the data.) The Guidance Package for this Standard details the steps that must be taken by registrants to comply with Section 3(c)(2)(B).

## Amendments to the Standard

Applications for registration which propose uses or formulations that are not presently covered by the Standard, or which present product compositions, product chemistry data, hazard data, toxicity levels, or labeling that do not meet the requirements of the Standard, will automatically be considered by the Agency to be requests for amendments to the Standard. In response to such applications, the Agency may request additional data to support the proposed amendment to the Standard, or may deny the application for registration on the grounds that the proposed product would cause unreasonable adverse effects to the environment. In the former case, when additional data have been satisfactorily supplied, and providing that the data do not indicate the potential for unreasonable adverse effects, the Agency will then amend the Standard to cover the new registration.

Each Registration Standard is based upon all data and information available to the Agency's reviewers on a particular date prior to the publication date. This "cut-off" date is stated at the beginning of the second chapter. Any subsequent data submissions and any approved amendments will be incorporated into the Registration Standard by means of addenda, which are available for inspection at EPA in Washington, D.C., or copies of which may be requested from the Agency. When all the present "data gaps" have been filled and the submitted data have been reviewed, the Agency will revise the Registration Standard. Thereafter, when the Agency determines that the internally maintained addenda have significantly altered the conditions for registration under the Standard, the document will be updated and re-issued for publication.

While the Registration Standard discusses only the uses and hazards of products containing the designated active ingredient(s), the Agency is also concerned with the potential hazards of some inert ingredients and impurities. Independent of the development of any one Standard, the Agency has initiated the evaluation of some inert pesticide ingredients. Where the Agency has identified inert ingredients of concern in a specific product to which the Standard applies, these ingredients will be pointed out in the Guidance Package.

# Chapter II

## Agency Position on Dichlone

### Regulatory Position for Dichlone

Dichlone as described in this Standard may be registered for sale, distribution, reformulation, and use in the United States. The Agency has considered the limited amount of scientific data obtained from the open literature as of January 15, 1980, and the data submitted by the registrants up through the time of publication of this Standard. In view of this information, the Agency finds that none of the risk criteria found in section 162.11(a) of Title 40 of the U.S. Code of Federal Regulations have been met or exceeded for dichlone. Products currently registered may be reregistered subject to the requirements for data submission. New dichlone products may be registered under this Standard and are subject to the same requirements.

### Criteria for Registration Under the Standard

To be subject to this Standard, dichlone products must meet the following conditions:

1. The product must meet the composition standards specified below.

2. The product must meet the acute toxicity standards specified below.

3. The product must meet the labeling standards specified below.

4. The applicant must submit all data specified in the section Data Requirements and Data Gaps.

5. The applicant must offer, when applicable, to pay compensation to the extent required by 3(c)(1)(D) and 3(c)(2)(D) of the Federal Insecticide, Fungicide and Rodenticide Act [FIFRA], as amended, 7 U.S.C. 136(c)(1)(D) and 136(c)(2)(D).

6. The applicant must request that the Agency use all applicable data cited in the Standard in making the registration decision.

7. The applicant must submit the application package in the required form as specified in this Standard and the accompanying guidance package.

The following two companies have submitted data in support of dichlone registration, and have not waived their rights to compensation for these data: FMC Corporation and Uniroyal.

## Product Composition Standards

### Manufacturing- Use Dichlone*

To be covered under this Standard, manufacturing-use dichlone products with any percentage of active ingredient (a.i.) are acceptable with appropriate certification of limits. Nevertheless, given current manufacturing-use product grades and methods of synthesis, the Agency expects that most technical material will range above 90% a.i.

The Agency identified the possibility of lead contamination during manufacture of dichlone. Therefore, for dichlone products to be registered under this Standard, identification and certification of all impurities in the technical product must be made.

### Formulated Dichlone Products**

To be covered under this Standard, formulated dichlone products with any percentage of ingredients are acceptable with appropriate certification of limits.

Inert ingredients in food-use formulations must be cleared for such use under 40 CFR 180.1001.

## Acute Toxicity Standards

### Manufacturing- Use Dichlone

The Agency will consider registration of manufacturing-use dichlone products which have established Toxicity Categories I through IV ratings for each of the following acute effects:

Acute Oral Toxicity
Acute Dermal Toxicity
Acute Inhalation Toxicity
Primary Eye Irritation
Primary Dermal Irritation

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*As used in this Standard, "manufacturing-use" means any pesticide product that is used solely for the manufacturing of end-use pesticide products. This term includes both technical and formulation intermediate products.

**Formulated dichlone products include: Wettable Powder, Dust, Flowable Concentrate, and Solution-Ready-To-Use.

## Formulated Dichlone Products

To be registered for domestic use under this Standard, formulated dichlone products must have Toxicity Category III or IV ratings for each of the following acute effects:

Acute Oral Toxicity
Acute Dermal Toxicity
Acute Inhalation Toxicity
Primary Eye Irritation
Primary Dermal Irritation

To be registered for nondomestic use, formulated dichlone products must have Toxicity Categories II, III, or IV for acute oral, acute dermal, and acute inhalation toxicity. For primary eye and skin irritation the product may have a Toxicity Category I through IV.

## Labeling Standards

The formatting requirements are contained in 40 CFR 162.10. The subsections below explain how each heading will be incorporated.

### Use Patterns: Manufacturing-Use Dichlone

To be registered under this Standard, manufacturing-use dichlone must be formulated into end-use fungicides and herbicides. Manufacturing-use pesticides may not include end-use directions.

### Use Patterns: Formulated Dichlone Products

To be registered under this Standard, formulated dichlone products may be used only as a fungicide on apples, cherries, peaches, plums and prunes, strawberries, beans, celery, tomatoes, potatoes, roses and azaleas; and as a herbicide in aquatic areas. The Agency finds that current dosage rates and application methods are acceptable under this Standard.

### Product Chemistry

All dichlone products must list the active ingredient as 2,3-dichloro-1,4-naphthoquinone.

Active ingredient:

| | |
|---|---|
| Dichlone (2,3-dichloro-1,4-naphthoquinone)........ | 0-100% |
| Inert Ingredients.................................. | 0-100% |
| Total.............................................. | 100% |

### Physical Hazard: Precautionary Labeling

The labeling of manufacturing-use and formulated dichlone products must bear appropriate warnings in accordance with the nature of the physical/chemical properties of the product. At the present, there have been no data submitted to the Agency detailing any physical hazards of manufacturing-use or formulated dichlone products.

Human Hazard: Precautionary Labeling

The required hazard warnings and first aid statements on all manufacturing-use and formulated dichlone product labels must correspond to the Toxicity Category for each acute effect. Refer to 40 CFR 162.10(h)(2)(B) for the required labeling for each Toxicology Category.

Ecological Effects

All labels for formulated dichlone products intended for use as fungicides and as algaecides in swimming pools must include the following warning:

"This pesticide is toxic to fish and other aquatic organisms. Do not contaminate water by cleaning of equipment or disposal of wastes".

For technical and manufacturing-use products, the following must be added: "This pesticide is toxic to fish and other aquatic organisms. Do not discharge into lakes, ponds or public water unless in accordance with NPDES permit. For guidance, contact your Regional Office of the EPA".

All labels for formulated dichlone products intended for use as algaecides in lakes and ponds must include the following warning: "This pesticide is toxic to fish and other aquatic organisms. Fish may be killed at the label application rates. Do not apply to fish bearing waters."

All labels for food crop and ornamental uses must bear a statement similar to: "This pesticide is toxic to fish."

Environmental Fate

The Agency does not have adequate data on which to base changes to current environmental fate labeling requirements, and as such, registrants should retain their current labels.

Storage and Disposal

Appropriate storage and disposal information is required of all manufacturing-use and formulated dichlone products. For specific requirements, see 40 CFR 165.

## Data Requirements and Data Gaps

All registrants of dichlone products must fulfill the data requirements as summarized on pages 14 through 25. A full description of the data requirements can be found in the Proposed Guidelines for the Registration of pesticides in the United States, 43 FR 29696, July 10, 1978; 43 FR 37336, August 22, 1978; and 45 FR 72948, November 3, 1980.

The Agency has not received acceptable acute toxicity data for any of the formulated dichlone products. Therefore, all required acute toxicity tests are needed for each of the following formulation types: 50% wettable powder; 2,3,6,and 9% dust; 50% flowable concentrate; 1.5, 4.9, and 5% flowable concentrate; and 1.5% solution ready to use.

Applicants are hereby advised that if the Agency does not receive commitments within the specified time frame from manufacturing-use dichlone producers to fill data gaps identified for the manufacturing-use product, manufacturing-use product registrations will be suspended. Formulators must then bear the burden of supplying the data if they want the manufacturing-use product to be available.

### Tolerance Reassessment

For dichlone, the following tolerances have been established: 3 ppm in or on apples, beans, celery, cherries, peaches, plums (fresh prunes) and tomatoes and 15 ppm in or on strawberries. Based on these established tolerances, the theoretical maximum residue contribution (TMRC) of dichlone to the human diet is calculated to be 0.4403 mg/day/1.5 kg diet. However, this TMRC is based on the above crop tolerances and these tolerances can no longer be supported with the available residue data. A tolerance reassessment is not possible at this time and will be performed when the required residue data are supplied and reviewed.

## REGULATORY RATIONALE

### Product Composition Standards

The Agency will consider for registration the formulated dichlone products which contain dichlone as the sole active ingredient if the products meet the acute toxicity standards for domestic use and nondomestic use if the inert ingredients have been cleared for food use under 40 CFR 180.1001.

### Acute Toxicity Limits

#### Manufacturing-Use Dichlone

The Agency will consider for registration all manufacturing-use dichlone products.

#### Formulated Dichlone Products

The Agency will consider for registration all formulated dichlone products. Use classification will be determined upon receipt of acute toxicity data. All formulated products for use on raw agricultural commodities must contain only those inert ingredients which are cleared under 40 CFR 180.1001.

### Use Patterns

To be registered under this Standard, formulated dichlone products may be used only as a fungicide on apples, cherries, peaches, plums and prunes, strawberries, beans, celery, tomatoes, potatoes, roses and azaleas; and as a herbicide in aquatic areas. The Agency finds that current dosage rates and application methods are acceptable under this Standard.

Manufacturing-use dichlone products may be registered for use only in the formulation of specific end-use products.

## Data Gaps

Data on acute toxicity are required for all formulated dichlone products. Dichlone's food use and the need for tolerance reassessment for those uses is the basis for dichlone's chronic toxicology data requirements. The aquatic use pattern of dichlone requires subchronic testing, teratogenicity, and mutagenicity data. The aquatic use also necessitates testing on the environmental fate of dichlone in water, as well as its chronic effects on wildlife. Product chemistry data pertaining to manufacturing-use as well as end-use products are needed. To support the establised tolerances, data will have to be submitted on the following: fate of dichlone residues in plants and animals, residue studies for the raw agricultural commodities and their by-products reflecting the latest registered uses and dosage rates, residue processing studies in apple pomace and tomato pulp, and studies reflecting the persistence of dichlone residues in water. The Office of Pesticide Programs (OPP) will transfer scientific information about dichlone to EPA's Office of Drinking Water (ODW) so that ODW may consider monitoring for dichlone residues in water, and if necessary, may initiate procedures for regulating those residues under the Safe Drinking Water Act. Additional hazard data received by OPP will be conveyed to ODW as required.

Table 1-1 Product Chemistry Data Requirements for Manufacturing Grade Dichlone by Composition Characteristics

| Guidelines Section | Data Requirement for Manufacturing Products | Composition Characteristics | Do we need it? | Do we have it? |
|---|---|---|---|---|
| 163.61-3 | Product identity and disclosure of ingredients | Manufacturing-use | Yes | Yes |
| 163.61-4 | Description of manufacturing process | Manufacturing-use | Yes | No |
| 163.61-5 | Discussion on formation of unintentional ingredients | Manufacturing-use | Yes | No |
| 163.61-6 | Declaration and certification of ingredient limits | Manufacturing-use | Yes | No |
| 163.61-7 | Product analytical methods and data | Manufacturing-use | Yes | No |
| 163.61-8(1) | Color | Technical | Yes | Yes |
| 163.61-8(2) | Odor | Technical | Yes | No |
| 163.61-8(3) | Melting point | Technical | Yes | Yes |
| 163.61-8(4) | Solubility | Technical | Yes | Yes |
| 163.61-8(5) | Stability | Technical | Yes | Yes |
| 163.61-8(6) | Octanal/Water partition coefficient | Technical | Yes | No |
| 163.61-8(7) | Physical state | Technical & manufacturing use | Yes | Yes |
| 163.61-8(8) | Density or specific gravity | Technical & manufacturing use | Yes | Yes |
| 163.61-8(9) | Boiling point | Technical & manufacturing use | No | |
| 163.61-8(10) | Vapor pressure | Technical & manufacturing use | Yes | No |
| 163.61-8(11) | pH | Technical & manufacturing use | Yes | No |
| 163.61-8(12) | Storage stability | Manufacturing-use | Yes | Yes |
| 163.61-8(13) | Flammability | Manufacturing-use | Yes | Yes |
| 163.61-8(14) | Oxidizing or reducing action | Manufacturing use | Yes | No |
| 163.61-8(15) | Explosiveness | Manufacturing-use | Yes | No |
| 163.61-8(16) | Miscibility | Manufacturing-use | No | |
| 163.61-8(17) | Viscosity | Manufacturing use | No | |
| 163.61-8(18) | Corrosion characteristics | Manufacturing-use | Yes | No |

Table 1-2 Product Chemistry-- Data Requirements for End-Use Dichlone Products by Composition Characteristics

| Guidelines Section | Data Requirement for End-Use Products | Composition Characteristics | Do we need it? | Do we have it? |
|---|---|---|---|---|
| 163.61-3 | Product identity and disclosure of ingredients | 50%WP | Yes | Yes |
| | | 2,3,6,9%D | Yes | Yes |
| | | 50% FC | Yes | Yes |
| | | 1.5%, 4.9%, 5% FC; 1.5% RTU | Yes | Yes |
| 163.61-4 | Description of manufacturing process | 50%WP | Yes | No |
| | | 2,3,6,9%D | Yes | No |
| | | 50% FC | Yes | No |
| | | 1.5%, 4.9%, 5% FC; 1.5% RTU | Yes | No |
| 163.61-5 | Discussion on formation of unintentional ingredients | 50%WP | Yes | No |
| | | 2,3,6,9%D | Yes | No |
| | | 50%FC | Yes | No |
| | | 1.5%, 4.9%, 5% FC; 1.5% RTU | Yes | No |
| 163.61-6 | Declaration and certification of ingredient limits | 50%WP | Yes | No |
| | | 2,3,6,9%D | Yes | No |
| | | 50% FC | Yes | No |
| | | 1.5%, 4.9%, 5% FC; 1.5% RTU | Yes | No |
| 163.61-7 | Product analytical methods and data | 50%WP | Yes | No |
| | | 2,3,6,9%D | Yes | No |
| | | 50% FC | Yes | No |
| | | 1.5%, 4.9%, 5% FC; 1.5% RTU | Yes | No |
| 163.61-8(1) | Color | 50%WP | Yes | No |
| | | 2,3,6,9%D | Yes | No |
| | | 50% FC | Yes | No |
| | | 1.5%, 4.9%, 5% FC; 1.5% RTU | Yes | No |
| 163.61-8(2) | Odor | 50%WP | Yes | No |
| | | 2,3,6,9%D | Yes | No |
| | | 50% FC | Yes | No |
| | | 1.5%, 4.9%, 5% FC; 1.5% RTU | Yes | No |

Table I-2 Product Chemistry-- Data Requirements for End-Use Dichlone Products by Composition Characteristics (cont.)

| Guidelines Section | Data Requirement for End-Use Products | Composition Characteristics | Do we need it? | Do we have it? |
|---|---|---|---|---|
| 163.61-8(7) | Physical state | 50%WP | Yes | Yes |
| | | 2,3,6,9%D | Yes | Yes |
| | | 50% FC | Yes | Yes |
| | | 1.5%, 4.9%, 5% FC; 1.5% RTU | Yes | Yes |
| 163.61-8(8) | Density or specific gravity | 50%WP | Yes | No |
| | | 2,3,6,9%D | Yes | No |
| | | 50% FC | Yes | No |
| | | 1.5%, 4.9%, 5% FC; 1.5% RTU | Yes | No |
| 163.61-8(9) | Boiling point | 50%WP | No | |
| | | 2,3,6,9%D | No | |
| | | 50% FC | Yes | No |
| | | 1.5%, 4.9%, 5% FC; 1.5% RTU | Yes | No |
| 163.61-8(10) | Vapor pressure | 50%WP | Yes | No |
| | | 2,3,6,9%D | Yes | No |
| | | 50% FC | Yes | No |
| | | 1.5%, 4.9%, 5% FC; 1.5% RTU | Yes | No |
| 163.61-8(11) | pH | 50%WP | Yes | No |
| | | 2,3,6,9%D | Yes | No |
| | | 50% FC | Yes | No |
| | | 1.5%, 4.9%, 5% FC; 1.5% RTU | Yes | No |
| 163.61-8(12) | Storage stability | 50%WP | Yes | No |
| | | 2,3,6,9%D | Yes | No |
| | | 50% FC | Yes | No |
| | | 1.5%, 4.9%, 5% FC; 1.5% RTU | Yes | No |
| 163.61-8(13) | Flammability | 50%WP | Yes | No |
| | | 2,3,6,9%D | Yes | No |
| | | 50% FC | Yes | No |
| | | 1.5%, 4.9%, 5% FC; 1.5% RTU | Yes | No |

Table 1-2 Product Chemistry-- Data Requirements for End-Use Dichlone Products by Composition Characteristics (cont.)

| Guidelines Section | Data Requirement for End-Use Products | Composition Characteristics | Do we need it? | Do we have it? |
|---|---|---|---|---|
| 163.61-8(14) | Oxidizing or reducing action | 50%WP | Yes | No |
| | | 2,3,6,9%D | Yes | No |
| | | 50% FC | Yes | No |
| | | 1.5%, 4.9%, 5% FC; 1.5% RTU | Yes | No |
| 163.61-8(15) | Explosiveness | 50%WP | Yes | No |
| | | 2,3,6,9%D | Yes | No |
| | | 50% FC | Yes | No |
| | | 1.5%, 4.9%, 5% FC; 1.5% RTU | Yes | No |
| 163.61-8(16) | Miscibility | 50%WP | No | |
| | | 2,3,6,9%D | No | |
| | | 50% FC | Yes | No |
| | | 1.5%, 4.9%, 5% FC; 1.5% RTU | Yes | No |
| 163.61-8(17) | Viscosity | 50%WP | No | |
| | | 2,3,6,9%D | No | |
| | | 50% FC | Yes | No |
| | | 1.5%, 4.9%, 5% FC; 1.5% RTU | Yes | No |
| 163.61-8(18) | Corrosion characteristics | 50%WP | Yes | No |
| | | 2,3,6,9%D | Yes | No |
| | | 50% FC | Yes | No |
| | | 1.5%, 4.9%, 5% FC; 1.5% RTU | Yes | No |
| 163.61-8(19) | Dielectric breakdown voltage | 50%WP | No | |
| | | 2,3,6,9%D | No | |
| | | 50% FC | No | |
| | | 1.5%, 4.9%, 5% FC; 1.5% RTU | No | |

Table II Environmental Fate-- Dichlone Generic Data Requirements by Use Patterns

| Guidelines Section | Generic Data Requirement | Use Pattern | Is data required? | Does EPA have Data? | Must data be submitted? |
|---|---|---|---|---|---|
| 163.62-7(b) | Hydrolysis | Food Crops | Yes | Yes | Yes |
| | | Ornamentals | Yes | Yes | Yes |
| | | Swimming Pools | Yes | Yes | Yes |
| | | Lakes and Ponds | Yes | Yes | No |
| 163.62-7(c) | Photodegradation | Food Crops | Yes | No | Yes |
| | | Ornamentals | Yes | No | Yes |
| | | Swimming Pools | Yes | No | Yes |
| | | Lakes and Ponds | Yes | No | Yes |
| 163.62-8(b) | Aerobic soil metabolism | Food Crops | Yes | Yes | Yes |
| | | Ornamentals | Yes | Yes | Yes |
| | | Swimming Pools | No | | |
| | | Lakes and Ponds | No | | |
| 163.62-8(c) | Anaerobic soil metabolism | Food Crops | Yes | No | Yes |
| | | Ornamentals | No | | |
| | | Swimming Pools | No | | |
| | | Lakes and Ponds | No | | |
| 163.62-8(d) | Anaerobic aquatic metabolism | Food Crops | No | | |
| | | Ornamentals | No | | |
| | | Swimming Pools | Yes | No | Yes |
| | | Lakes and Ponds | Yes | No | Yes |
| 163.62-8(e) | Aerobic aquatic metabolism | Food Crops | No | | |
| | | Ornamentals | No | | |
| | | Swimming Pools | Yes | No | Yes |
| | | Lakes and Ponds | Yes | No | Yes |
| 163.62-8(f)(2) | Effects of microbes on pesticide | Food Crops | Yes | No | Yes |
| | | Ornamentals | Yes | No | Yes |
| | | Swimming Pools | Yes | No | Yes |
| | | Lakes and Ponds | Yes | No | Yes |
| 163.62-8(f)(3) | Effects of pesticide on microbes | Food Crops | Yes | Yes | Yes |
| | | Ornamentals | Yes | Yes | Yes |
| | | Swimming Pools | Yes | Yes | Yes |
| | | Lakes and Ponds | Yes | Yes | Yes |
| 163.62-8(g) | Activated sludge metabolism | Food Crops | Yes | No | Yes |
| | | Ornamentals | Yes | No | Yes |
| | | Swimming Pools | Yes | No | Yes |
| | | Lakes and Ponds | No | | |
| 163.62-9(b) | Leaching | Food Crops | Yes | Yes | Yes |
| | | Ornamentals | Yes | Yes | Yes |
| | | Swimming Pools | Yes | Yes | Yes |
| | | Lakes and Ponds | Yes | Yes | Yes |
| 163.62-9(c) | Volatility | Food Crops | No | | |
| | | Ornamentals | No | | |
| | | Swimming Pools | No | | |
| | | Lakes and Ponds | No | | |

Table II Environmental Fate-- Dichlone Generic Data Requirements by Use Patterns (cont.)

| Guidelines Section | Generic Data Requirement | Use Pattern | Is data required? | Does EPA have Data? | Must data be submitted? |
|---|---|---|---|---|---|
| 163.62-9(d) | Adsorption/desorption | Food Crops | Yes | No | Yes |
| | | Ornamentals | Yes | No | Yes |
| | | Swimming Pools | Yes | No | Yes |
| | | Lakes and Ponds | Yes | No | Yes |
| 163.62-9(e) | Water dispersal | Food Crops | No | | |
| | | Ornamentals | No | | |
| | | Swimming Pools | Yes | No | Yes |
| | | Lakes and Ponds | Yes | No | Yes |
| 163.62-10(b) | Terrestrial field dissipation | Food Crops | Yes | Yes | Yes |
| | | Ornamentals | Yes | Yes | Yes |
| | | Swimming Pools | No | | |
| | | Lakes and Pools | No | | |
| 163.62-10(c) | Aquatic field dissipation | Ornamentals | Yes | No | Yes |
| | | Swimming Pools | Yes | No | Yes |
| | | Lakes and Ponds | Yes | No | Yes |
| 163.62-10(d) | Terrestrial/Aquatic (forest) ecosystem residue | Food Crops | No | | |
| | | Ornamentals | No | | |
| | | Swimming Pools | No | | |
| | | Lakes and Ponds | No | | |
| 163.62-10(e) | Aquatic Impact Uses | Food Crops | Yes | No | Yes |
| | | Ornamentals | Yes | No | Yes |
| | | Swimming Pools | Yes | No | Yes |
| | | Lakes and Ponds | Yes | No | Yes |
| 163.62-10(f) | Combination and tank mixes | Food Crops | Yes | No | Yes |
| | | Ornamentals | Yes | No | Yes |
| | | Swimming Pools | Yes | No | Yes |
| | | Lakes and Ponds | Yes | No | Yes |
| 163.62-11(b) | Rotational Crops | Food Crops | Yes | No | Yes |
| | | Ornamentals | Yes | No | Yes |
| | | Swimming Pools | No | | |
| | | Lakes and Ponds | No | | |

Table III-1 Ecological Effects-- Data Requirements for End-Use Dichlone Products by Composition Characteristics

| Guidelines Section | Data Requirement for End-Use Products | Composition Characteristics | Do we need it? | Do we have it? |
|---|---|---|---|---|
| 163.71-5(1) | Cage or pen field test* | 50%WP | No* | |
| | | 2,3,6,9%D | No* | |
| | | 50% FC | No* | |
| | | 1.5% 4.9%, 5% FC; 1.5% RTU | No* | |
| 163.71-5(2) | Full scale field test* | 50%WP | No* | |
| | | 2,3,6,9%D | No* | |
| | | 50% FC | No* | |
| | | 1.5%, 4.9%, 5% FC; 1.5% RTU | No* | |
| 163.72-1 | Fish acute $LC_{50}$ rainbow trout, bluegill | 50%WP | Yes | No |
| | | 2,3,6,9%D | No | |
| | | 50% FC | No | |
| | | 1.5%, 4.9%, 5% FC; 1.5% RTU | Yes | No |
| 163.72-2 | Acute toxicity to aquatic invertebrates | 50%WP | Yes | No |
| | | 2,3,6,9%D | No | |
| | | 50% FC | No | |
| | | 1.5%, 4.9%, 5% FC; 1.5% RTU | Yes | No |
| 163.72-3 | Acute toxicity to estuarine and marine organism | 50%WP | No | |
| | | 2,3,6,9%D | No | |
| | | 50% FC | No | |
| | | 1.5%, 4.9%, 5% FC; 1.5% RTU | No | |
| 163.72-6(a)(1) | Short term simulated field test | 50%WP | Yes | No |
| | | 2,3,6,9%D | No* | |
| | | 50% FC | No* | |
| | | 1.5% 4.9%, 5% FC; 1.5% RTU | Yes* | No |
| 163.72-6(a)(2) | Long term simulated field test | 50%WP | No* | |
| | | 2,3,6,9%D | No* | |
| | | 50% FC | No* | |
| | | 1.5, 5%FC, 1.5% RTU | No* | |

* When additional data is received and evaluated, these studies may be required.

Table III-2 Ecological Effects-- Generic Data Requirements for Dichlone by Use Patterns

| Guidelines Section | Generic Data Requirement | Use Pattern | Is data required? | Does EPA Have Data? | Must data be submitted? |
|---|---|---|---|---|---|
| 163.62-11(c) | Irrigated Crops | Food Crops | Yes | No | Yes |
| | | Ornamentals | Yes | No | Yes |
| | | Swimming Pools | No | | |
| | | Lakes and Ponds | No | | |
| 163.62-11(d) | Fish accumulation | Food Crops | Yes | No | Yes |
| | | Ornamentals | Yes | No | Yes |
| | | Swimming Pools | No | | |
| | | Lakes and Ponds | Yes | No | Yes |
| 163.62-11(e) | Special study - Aquatic non-crop | Food Crops | Yes | No | Yes |
| | | Ornamentals | No | | |
| | | Swimming Pools | No | | |
| | | Lakes and Ponds | Yes | No | Yes |
| 163.71-1 | Avian Single Dose $LD_{50}$ | Food Crops | Yes | No | Yes |
| | | Ornamentals | Yes | No | Yes |
| | | Swimming Pools | Yes | No | Yes |
| | | Lakes and Ponds | Yes | No | Yes |
| 163.71-2 | Avian dietary $LC_{50}$ - mallard - bobwhite quail | Food Crops | Yes | Yes | No |
| | | Ornamentals | Yes | Yes | No |
| | | Swimming Pools | Yes | Yes | No |
| | | Lakes and Ponds | Yes | Yes | No |
| 163.71-3 | Mammalian acute toxicity | Food Crops | No | | |
| | | Ornamentals | No | | |
| | | Swimming Pools | No | | |
| | | Lakes and Ponds | No | | |
| 163.71-4 | Avian reproduction a)mallard b)bobwhite quail | Food Crops | Yes | No | Yes |
| | | Ornamentals | No | | |
| | | Swimming Pools | No | | |
| | | Lakes and Ponds | No | | |
| 163.72-1 | Fish acute $LC_{50}$ - rainbow trout, bluegill | Food Crops | Yes | Yes | No |
| | | Ornamentals | Yes | Yes | No |
| | | Swimming Pools | Yes | Yes | No |
| | | Lakes and Ponds | Yes | Yes | No |
| 163.72-2 | Acute toxicity to aquatic invertebrates | Food Crops | Yes | Yes | No |
| | | Ornamentals | Yes | Yes | No |
| | | Swimming Pools | Yes | Yes | No |
| | | Lakes and Ponds | Yes | Yes | No |
| 163.72-3 | Acute toxicity to estuarine and marine organisms | Food Crops | No | | |
| | | Ornamentals | No | | |
| | | Swimming Pools | No | | |
| | | Lakes and Ponds | No | | |
| 163.72-4 | Embryo larvae and life cycle studies/fish and aquatic invertebrates | Food Crops | No* | | |
| | | Ornamentals | No* | | |
| | | Swimming Pools | No* | | |
| | | Lakes and Ponds | No* | | |
| 163.72-5 | Aquatic organisms toxicity and residue studies | Food Crops | No* | | |
| | | Ornamentals | No* | | |
| | | Swimming Pools | No* | | |
| | | Lakes and Ponds | No* | | |

*When additional data is received and evaluated, these studies may be required.

Table III-2 Ecological Effects-- Generic Data Requirements for Dichlone by Use Patterns (cont.)

| Guidelines Section | Generic Data Requirement | Use Pattern | Is data required? | Does EPA Have Data? | Must data be submitted? |
|---|---|---|---|---|---|
| 163.122-1 | Seed Germination | Food Crops | Yes | Yes | |
| | | Ornamentals | Yes | Yes | |
| | | Swimming Pools | No | | |
| | | Lakes and Ponds | Yes | Yes | Yes |
| 163.122-1 | Vegetative Vigor | Food Crops | Yes | No | Yes |
| | | Ornamentals | Yes | No | Yes |
| | | Swimming Pools | No | | |
| | | Lakes and Ponds | Yes | No | Yes |
| 163.122-2 | Aquatic Macrophytes | Food Crops | Yes | Yes | No |
| | | Ornamentals | Yes | Yes | No |
| | | Swimming Pools | No | | |
| | | Lakes and Ponds | Yes | Yes | No |
| 163.122-2 | Algae | Food Crops | Yes | Yes | No |
| | | Ornamentals | Yes | Yes | No |
| | | Swimming Pools | No | | |
| | | Lakes and Ponds | Yes | Yes | No |
| 163.125-3 | Nitogen Fixation Potential | Food Crops | Yes | Yes | No |
| | | Ornamentals | Yes | Yes | No |
| | | Swimming Pools | Yes | Yes | No |
| | | Lakes and Ponds | Yes | Yes | No |

Table IV-1 Toxicology-- Data Requirements for Dichlone Products by Composition Characteristics

| Guidelines Section | Data Requirement | Composition Characteristics | Do we need it? | Do we have it? |
|---|---|---|---|---|
| 163.81-1 | Acute Oral toxicity | Manufacturing-Use | Yes | Yes |
| | | 50%WP | Yes | No |
| | | 2,3,6,9%D | Yes | No |
| | | 50% FC | Yes | No |
| | | 1.5%, 4.9%, 5% FC; 1.5% RTU | Yes | No |
| 163.81-2 | Acute dermal toxicity | Manufacturing Use | Yes | No |
| | | 50%WP | Yes | No |
| | | 2,3,6,9%D | Yes | No |
| | | 50% FC | Yes | No |
| | | 1.5%, 4.9%, 5% FC; 1.5% RTU | Yes | No |
| 163.81-3 | Acute inhalation toxicity | Manufacturing-Use | Yes | No |
| | | 50%WP | Yes | No |
| | | 2,3,6,9%D | Yes | No |
| | | 50% FC | Yes | No |
| | | 1.5% 4.9%, 5% FC; 1.5% RTU | Yes | No |
| 163.81-4 | Primary eye irritation | Manufacturing-Use | Yes | No |
| | | 50%WP | Yes | No |
| | | 2,3,6,9%D | Yes | No |
| | | 50% FC | Yes | No |
| | | 1.5%, 4.9%, 5% FC; 1.5% RTU | Yes | No |
| 163.81-5 | Primary dermal irritation | Manufacturing-Use | Yes | No |
| | | 50%WP | Yes | No |
| | | 2,3,6,9%D | Yes | No |
| | | 50% FC | Yes | No |
| | | 1.5%, 4.9%, 5% FC; 1.5% RTU | Yes | No |
| 163.81-6 | Dermal sensitization | Manufacturing-Use | Yes | No |
| | | 50%WP | Yes | No |
| | | 2,3,6,9%D | Yes | No |
| | | 50% FC | Yes | No |
| | | 1.5% 4.9%, 5% FC; 1.5% RTU | Yes | No |

Table IV-2 Toxicology-- Generic Data Requirements for Dichlone by Use Patterns

| Guidelines Section | Generic Data Requirement | Use Pattern | Is data required? | Does EPA have Data? | Must data be submitted? |
|---|---|---|---|---|---|
| 163.81-1 | Acute Oral Toxicity | Food Crops | Yes | Yes | No |
| | | Ornamentals | Yes | Yes | No |
| | | Swimming Pools | Yes | Yes | No |
| | | Lakes and Ponds | No | | |
| 163.81-2 | Acute Dermal Toxicity | Food Crops | Yes | No | Yes |
| | | Ornamentals | Yes | No | Yes |
| | | Swimming Pools | Yes | No | Yes |
| | | Lakes and Ponds | No | | |
| 163.81-3 | Acute inhalation toxicity | Food Crops | Yes | No | Yes |
| | | Ornamentals | Yes | No | Yes |
| | | Swimming Pools | Yes | No | Yes |
| | | Lakes and Ponds | No | | |
| 163.81-7 | Acute delayed neurotoxicity | Food Crops | No | | |
| | | Ornamentals | No | | |
| | | Swimming Pools | No | | |
| | | Lakes and Ponds | No | | |
| 163.82-1 | Subchronic oral dosing | Food Crops | Yes | Yes | Yes |
| | | Ornamentals | Yes | Yes | Yes |
| | | Swimming Pools | Yes | Yes | Yes |
| | | Lakes and Ponds | No | | |
| 163.82-2 | Subchronic 21 day dermal toxicity | Food Crops | Yes | No | No |
| | | Ornamentals | Yes | No | No |
| | | Swimming Pools | No | | |
| | | Lakes and Ponds | No | | |
| 163.82-3 | Subchronic 90 day dermal toxicity | Food Crops | Yes | No | Yes |
| | | Ornamentals | Yes | No | Yes |
| | | Swimming Pools | Yes | No | Yes |
| | | Lakes and Ponds | Yes | No | Yes |
| 163.82-4 | Subchronic inhalation toxicity | Food Crops | No | | |
| | | Ornamentals | No | | |
| | | Swimming Pools | No | | |
| | | Lakes and Ponds | No | | |
| 163.82-5 | Subchronic neurotoxicity | Food Crops | No | | |
| | | Ornamentals | No | | |
| | | Swimming Pools | No | | |
| | | Lakes and Ponds | No | | |
| 163.83-1 | Chronic feeding | Food Crops | Yes | Yes | Yes |
| | | Ornamentals | Yes | Yes | Yes |
| | | Swimming Pools | Yes | Yes | Yes |
| | | Lakes and Ponds | No | | |

Table IV-2 Toxicology-- Generic Data Requirements for Dichlone by Use Patterns (cont.)

| Guidelines Section | Generic Data Requirement | Use Pattern | Is data required? | Does EPA have Data? | Must data be submitted? |
|---|---|---|---|---|---|
| 163.83-2 | Oncogenicity | Food Crops | Yes | Yes | Yes |
| | | Ornamentals | Yes | Yes | Yes |
| | | Swimming Pools | Yes | Yes | Yes |
| | | Lakes and Ponds | No | | |
| 163.83-3 | Teratogenicity | Food Crops | Yes | No | Yes |
| | | Ornamentals | Yes | No | Yes |
| | | Swimming Pools | Yes | No | Yes |
| | | Lakes and Ponds | No | | |
| 163.83-4 | Reproduction | Food Crops | Yes | Yes | Yes |
| | | Ornamentals | Yes | Yes | Yes |
| | | Swimming Pools | Yes | Yes | Yes |
| | | Lakes and Ponds | No | | |
| 163.84-1 | Mutagenicity | Food Crops | Yes | No | Yes |
| | | Ornamentals | Yes | No | Yes |
| | | Swimming Pools | Yes | No | Yes |
| | | Lakes and Ponds | No | | |
| 163.85-1 | Metabolism | Food Crops | Yes | No | Yes |
| | | Ornamentals | Yes | No | Yes |
| | | Swimming Pools | Yes | No | Yes |
| | | Lakes and Ponds | No | | |

# Chapter III

## Product Chemistry Chapter

### Introduction

FIFRA 3(c)(2)(A) requires the Agency to establish guidelines for registering pesticides in the United States. The Agency requires registrants to provide quantitative data on all active ingredients, and provide data on manufacturing impurities and added inerts, which are equal to or greater than 0.1% of the product by weight.

To establish the composition of products proposed for registration, the Agency requires data and information not only on the manufacturing and formulation processes, but also a discussion on the formation of manufacturing impurities and other product ingredients, intentional and unintentional. Further to assure that the composition of the product as marketed will not vary from the composition evaluated at the time of registration, applicants are required to submit a statement certifying upper and lower composition limits for the added ingredients, and upper limits only for some unintentional ingredients. Subpart D suggests specific precision limits for ingredients based on the percentage of ingredient and the standard deviation of the analytical method.

In addition to the data on product composition, the Agency also requires data to establish the physical and chemical properties of both the pesticide active ingredient and its formulations. For example, data are needed concerning the identity and physical state of the active ingredient (e.g., solubility). Data are also required on the properties of the formulated product to establish labeling cautions (e.g., flammability, corrosiveness or storage stability). The Agency uses these data to characterize each pesticide and to determine its environmental and health hazards.

### DISCIPLINARY REVIEW

Chemistry Profile
Data Requirements and Data Gaps
Required Labeling

### Chemistry Profile

Technical dichlone contains a minimum of 95 percent of the active ingredient (2,3-dichloro-1,4-naphthoquinone). Technical dichlone is a yellow to brownish-yellow crystalline or powdery substance. Dichlone is relatively stable to light and heat. Its decomposition by light is accelerated while it is in solution and it can be sublimed at elevated temperatures. It is practically insoluble in water but very soluble in various organic solvents like xylene, dioxane, benzene, and chloroform. Specific gravity is 1.70 at 25°C, melting point range 188°C - 194°C. Technical dichlone is used for the formulation of end-use products, accordingly it is a "manufacturing-use product."

Based on the data reviewed, a technical pesticide product containing dichlone will have an equivalent concentration of active ingredient, the same identifiable non 2,3-dichloro-1,4-naphthoquinone components, and physical/chemical properties comparable to those described in this chapter. Data have been provided on the composition of each of the registered products, and are in the confidential statement of formula filed in the Registration Division, OPP. All the inerts listed in the confidential statements of formula are cleared for use on food or feed under Section 180.1001 of 40 CFR. The majority of the products are registered for agricultural use (food and nonfood uses) and some are registered for use as algaecides in swimming pools, ponds and lakes.

### Data Requirements and Data Gaps

All registrants of dichlone products must fulfill the data requirements as summarized on pages 14 through 17. A full description of the data requirements can be found in the Proposed Guidelines for the Registration of pesticides in the United States, 43 FR 29696, July 10, 1978.

### Required Labeling:

Ingredient Statement: The ingredient statement for the manufacturing-use product dichlone will list the active ingredient as:

"Dichlone (2,3-dichloro-1,4-naphthoquinone)......% min."

### Physical Hazard Precautionary Labeling

The labels of the technical and formulated products containing dichlone should bear appropriate warnings in accordance with the nature of physical/chemical properties to be submitted with the products at the time of reregistration.

## TOPICAL DISCUSSIONS

Corresponding to each of the Topical Discussions listed below is the number of the section in the 'Proposed Guidelines for Registering Pesticides in the United States' (43 FR 29696, July 10, 1978) which explains the minimum data that the Agency usually requires in order to adequately assess a pesticide's chemistry. Also under each of the topics is a reference to the section in the 'Proposed Guidelines'.

| Category of Test | Guideline Number |
|---|---|
| Chemical Identity | 163.61-3 |
| Manufacturing Process | 163.61-4 |
| Discussion on Formation of Unintentional Ingredients | 163.61-5 |
| Declaration and Certification of Ingredients | 163.61-6 |
| Product Analytical Methods and Data | 163.61-7 |
| Physical/Chemical Properties | 163.61-8 |

## CHEMICAL IDENTITY (163.61-3)

"Dichlone" is the generally accepted common name for 2,3-dichloro-1,4-naphthoquinone. Dichlone is approved as the official common name for 2,3-dichloro-1,4-naphthoquinone by the former Interdepartmental Committee on Pest Control, the British Standards Institution and the International Organization for Standardization.

The name "dichlone" will be routinely used in this standard.

Registered trade names for dichlone are: Dichlone, Quintar, Miraclear, and Phygon.

For the complete technical characterization of the compound, see the "Chemical Data Sheet" for dichlone in Table 1, following page.

## TABLE 1

### Dichlone Technical Chemical Characterization

Chemical name: 2,3-dichloro-1,4-naphthoquinone

Other name(s): Phygon, Quintar

Type: Fungicide

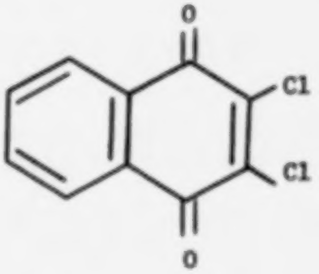
Shaughnessy #: 029601

C.A.S. #: 117-80-6

Chemical Formula: $C_{10}H_4O_2Cl_2$

Mol. Wt.: 227.05

Structural Formula:



Major Use: Fungicide on fruit trees and vegetables. Also used as an algaecide for the treatment of swimming pools, lakes, and ponds.

MANUFACTURING-PROCESS (163.61-4)

There are only two chemical companies which market technical dichlone, i.e.: FMC Corporation, Agricultural Chemical Division and Aceto Chemical Company, Inc. In 1971, FMC Corporation, in response to a request for product chemistry data, informed EPA that they do not manufacture dichlone but that they import the technical dichlone from Japan. The Aceto Chemical Company also imports its technical dichlone from Japan. No manufacturing process for the imported "Japanese" dichlone was reported, and no data have been submitted concerning the purity of the dichlone product.This constitutes a data gap.

The literature describes various methods of synthesizing dichlone:

1. The chlorination of sludge (a by-product in the production of phthalic anhydride from naphthalene), with the use of a catalyst and an inert solvent [Japanese Patent 67-17736; Tsuchida and Tachibana, 1967, MRID 05004864].

2. The chlorination of naphthalene in carbon tetrachloride and the oxidation of the chlorinated product by nitric acid and, in turn, chlorination of the oxidation product [U.S. Patent 3,433,812; Buzbee and Ecke, 1969, MRID 05001647].

3. The chlorination of sodium naphthionate in nitrobenzene [Nakahara et al., 1965, MRID 05003899].

4. The chlorination of 1,4-naphthoquinone by the use ot $FeCl_3H_2O$ and nitrobenzene [U.S. Patent 2,975,196; Sjoestrand, 1961, MRID 05001652].

5. The chlorination of 1,4-naphthoquinone in carbon tetrachloride and N-methyl-2-pyrolidone [Japanese Patent 76-113859; Watanabe et al., 1976, MRID 05004895].

6. The chlorination of 1,4-naphthoquinone in an organic solvent and N,N-dimethylformamide, N,N-dimethylacetamide or a higher n-n-dimethyl acylamide [British Patent 1,102,849; Chemische Fabrik von Heyden A.G., 1968, MRID 05002617].

7. The chlorination of naphthylamine salt and oxidation by nitric acid of the chlorinated product producing 2,3-dichloro-1,4-naphthoquinone [Japanese Patent 69-28300; Koromogawa et al., 1969, MRID 05005690].

8. The chlorination of 1,4-naphthoquinone in an organic solvent (mono chloro- benzene) and a catalyst comprised of a tri (low grade alkyl) phosphoric ester or a tris (low grade alkyl halide) phosphoric ester [Japanese Patent 78-98943; Matsuura et al., 1978, MRID 05009211]

Although each of these procedures is finely defined, no determination was made as to the presence and identification of manufacturing impurities.

The chemical reaction employed in the manufacture of the active ingredient may also produce harmful impurities. The presence of manufacturing impurities is dependent upon the sort of process used.

## DISCUSSION ON FORMATION OF UNINTENTIONAL INGREDIENTS (163.61-5)

The nature of the impurities found in the manufactured product depends upon the kind of manufacturing process used. FMC and Aceto have not submitted to the Agency the manufacturing process used to synthesize dichlone in Japan. Therefore, no predictions will be made concerning formation of unintentional impurities found.

## DECLARATION AND CERTIFICATION OF INGREDIENTS (163.61-6)

The Registration Standard includes the composition of technical dichlone, manufacturing-use dichlone and end-use formulations which contain the active ingredient. This information is needed to define the acceptable ranges of concentration allowable in registered products, to prescribe appropriate test material concentrations in hazard evaluation testing and later to estimate likely exposures to the active ingredient resulting from the handling or use of the products which contain it.

### Technical dichlone (manufacturing-use product)

There are no data on the certification of dichlone produced by Aceto Chemical Company, or FMC Chemical Company. This constitutes a data gap.

Information, posted by the U.S. Rubber Company in the Technical Formulations Handbook (United States Rubber Co., 1965, MRID 00001540) describes the technical dichlone as containing not less than 95 percent of the active ingredient 2,3-dichloro-1,4-naphthoquinone with the following specific particle size distribution, i.e.: the mean particle radius will range from 3.5 to 6.0 microns and particles with a radius of over 10 microns will be not more than 16 percent of the total. According to the above information, up to 5% of the technical impurities (including moisture) can be expected.

There are nine chemical companies registered to manufacture or formulate 21 products containing dichlone as a single active ingredient. There are 19 registered formulated products containing dichlone as a single active ingredient. However, they are not all registered for agricultural use. See Table 2, on the following page.

This Registration Standard for dichlone thus covers only those technical products within the above mentioned composition range for percentage of active ingredient. Accordingly, pesticide producers and formulators who wish to register a product containing dichlone that does not fall within this range of composition must petition the Agency to amend the standard.

## PRODUCT ANALYTICAL METHODS AND DATA (163.61-7)

In order to ensure that products contain only those percentages of active ingredient which they properly claim to contain, it is necessary to have available analytical methods which may be used to determine the concentration of active ingredient in each formulation.

Second, in the commercial production of pesticide chemicals, reactions between pesticide ingredients, reactions with packaging materials, as well as degradation during the long period in which some products may be stored

## Table 2

### Manufacturers and Formulators of Dichlone Products

| Manufacturer/Formulator | Product Name |
|---|---|
| FMC Corp., Agri. Chem. Div. | Dichlone 50WP Fungicide<br>Dichlone 3 Dust<br>Dichlone 2 Dust<br>Dichlone Technical<br>Dichlone 90% |
| Haviland Agri. Chem. Co. | Dichlone Dust No. 2<br>Dichlone Dust No. 3<br>Dichlone Dust No. 6 |
| E-Z-Flo Chemical Co. | E-Z-Flo Dichlone 3 Dust |
| Hopkins Agri. Chem. Corp. | Dichlone Wettable Powder Fungicide<br>Hopkins Quintar 5F |
| Aceto Chem. Co., Inc. | Dichlone Fungicide<br>Dichlone 50 WP |
| Paragon Swimming Pool Co., Inc. | Miraclear L<br>Miraclear P |
| Modern Pool Products, Inc. | Berkite 13 Algaecide<br>Berkite 4 |
| Agway, Inc. | Phygon 6D<br>Agway Phygon 9D<br>Agway Phygon 50W<br>Phygon 3D |

before use, can result in the formation of chemical impurities. Because of the potential toxicity of impurities, analytical methods must be provided for their assessment, both to improve the reliability of the Agency's hazard assessment and to ensure that marketed products conform to the standards of purity agreed upon by the pesticide producer.

Though methods for the identification and quantification of dichlone and possible impurities have not been submitted by the registered manufacturers of dichlone, the literature indicates various Thin Layer Chromatographic, Colorimetric and Spectrophotometric methods. These TLC, Colorimetric and Spectrophotometric methods for detecting and measuring dichlone in its registered formulations are described in Goza (1972, MRID 05001418) and Kilgore and White (1970, MRID 05001423). A method regarded as satisfactory for the determination of dichlone and its impurities is depicted in Kotakemori and Okada (1968, MRID 05004746). In this study an analytical gas chromatographic method reported the principal impurity of Japanese dichlone as 2-chloro-1,4-naphthoquinone ranging from 0.75 to 2.64%. Also, the presence of minute quantities of phthalic anhydride and other unidentified compounds was indicated.

The presence of the phthalic anhydride as an impurity suggests that the analyzed dichlone was manufactured by the sludge chlorination method (Tsuchida and Tachibana, 1967, MRID 05004864). The nature of the impurities found in the manufactured product depends upon the kind of manufacturing process used.

A toxicological feeding study indicates that technical dichlone fed to animals contained from 30-600 ppm of lead (FRL, 1952, MRID 00001513).

Although the referenced methods are regarded as satisfactory for identification, there is not enough analytical data (recoveries, background sensitivity, etc.) to determine whether or not these methods are adequate for registration purposes which includes regulatory enforcement.

The presence of all impurities in dichlone down to 0.1%, as is required by the proposed Registration Guidelines Sections 163.61-7(a)(2),(3) has not been reported.

## PHYSICAL/CHEMICAL PROPERTIES (163.61-8)

Some physical/chemical properties reported for manufacturing-use dichlone are:

Color: yellow to yellow-brownish crystals or powder (United States Rubber Co., 1965, MRID 00001540)

Odor: no information available, this is a data gap

Solubility: (United States Rubber Co., 1965, MRID 00001540) (grams per 100 g. of solution at $25^{\circ}$C) in:

| | |
|---|---|
| Water | 0.1 ppm |
| Dioxane | 6.2 g |
| Benzene | 4.1 g |

| | |
|---|---|
| Glacial Acetic Acid | 1.1 g |
| Ethyl Acetate | 1.8 g |
| Acetone | 2.3 g |
| Diethyl Ether | 0.37 g |
| Xylene | 5.6 g |
| o-dichlorobenzene | 4.2 g |
| Ethyl Alcohol | 0.38 g |
| Skelly Solve B | less than 1 g |
| Carbon Tetrachloride | less than 1 g |
| Dibutyl Phthalate | less than 1 g |
| Dimethyl Formamide | 4.2 g |
| Chloroform | 2.9 g |
| n-Heptane | 0.06 g |
| Mineral oil | 0.12 g |
| Toluene | 3.5 g |

Melting Point Range: 188°C - 194°C (United States Rubber Co., 1965, MRID 00001540)

Stability:

Dichlone is relatively stable to light and heat. Its decomposition by light can be accelerated by solution and it can be sublimed at elevated temperatures. Although it is stable to hydrolysis in neutral or acid solution, it reacts readily in an alkaline medium. This is evidenced by a reddish-purple color indicating the formation of 2-hydroxy-3-chloro-1,4 naphthoquinone (United States Rubber Co., 1965, MRID 00001540).

Octanol/water partition coefficient:

No coefficient has been reported for technical dichlone. This is a data gap.

Physical State:

Technical dichlone is a solid (United States Rubber Co., 1965, MRID 00001540).

Density, bulk density or specific gravity:

The specific gravity of technical dichlone is 1.70 at 25°C. The bulk density of technical dichlone is 4.5 lbs./gal. average (United States Rubber Co., 1965, MRID 00001540).

Vapor pressure:

No vapor pressure for technical dichlone is reported. This is a data gap.

pH:

No determinations of pH were reported. Technical dichlone is practically insoluble in water. Accordingly, no pH measurement is necessary. For the formulated products, which can be dispersed with water, pH determinations are needed.

Storage Stability:

No storage stability data for technical dichlone or any of its formulations have been submitted. Technical dichlone is claimed by the manufacturer to be indefinitely stable in closed containers (United States Rubber Co., 1965, MRID 00001540).

Flammability:

Technical dichlone is a noncombustible compound (United States Rubber Co., 1965, MRID 00001540).

Oxidizing or reducing action:

No data are reported on dichlone as a manufacturing-use product or as a formulated product. Although dichlone is stable to hydrolysis in neutral or acid solution it readily reacts in an alkaline medium.

Explosiveness:

No data are reported on the manufacturing-use product and formulated products of dichlone.

Miscibility:

No emulsifiable liquid products with dichlone as a single active ingredient have been registered, accordingly, no data regarding "miscibility" are required.

Viscosity:

No viscosity data are reported for any dichlone liquid formulated products.

Corrosion characteristics:

No data on the corrosiveness of dichlone on containers are reported.

## Dielectric breakdown voltage:

No data on dielectric breakdown voltage are required because dichlone is not used around electrical power lines and equipment.

## Submittal of samples:

Applicants for registration or reregistration will be notified at the time of application with regard to the submission of samples.

## PRODUCT CHEMISTRY BIBLIOGRAPHY

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# Chapter IV

## Environmental Fate Chapter

DISCIPLINARY REVIEW

Environmental Fate Profile
Use Profile
Data Gaps

### Environmental Fate Profile

The submitted data were insufficient to fully assess the environmental fate of dichlone.

A half-life of five days was determined for dichlone (commercial formulation) by a hydrolysis study conducted in a 1/30 molar phosphate buffer at pH 7. Dichlone dissipates more rapidly in a moist (17.5% water, pH 6.4) than in a dry (1.6% water, pH 6.2) silt loam soil. Dichlone exhibited a half-life of one day in the moist soil and one of almost three months in the dry soil. Although the soil study does not differentiate between hydrolytic and metabolic degradative processes, the hydrolysis and soil metabolism studies taken together do suggest that hydrolysis and perhaps metabolism are major degradative processes of dichlone.

Soil nitrification, as measured by changes in total soil nitrate levels, was not affected by dichlone at recommended application rates. However, dichlone reportedly inhibited formation of taproot nodules while stimulating formation of lateral root nodules. Overall nodulation induced by Rhizobium leguminosarum was about the same in treated and control plants. At concentrations between 0.5 and 0.9 ug/ml, dichlone inhibited E. coli growth. Light dependent growth of photoautotrophic and photoheterotrophic cultures of Rhodosprillum rubrum was inhibited by dichlone at 1 uM. Dichlone at $3 \times 10^{-5}$ M completely inhibited oxygen evolution and chlorophyll production and markedly decreased cell numbers of the alga Chlorella by 48 hours of exposure. These studies suggest that dichlone, at recommended application rates, has deleterious effects on microbial growth among a diverse group of microorganisms (bacteria and eukaryotic algae) studied and not just on the target organism, blue-green algae. For fungi, the response to dichlone is quite variable and an overall no-effect level cannot be established. An $EC_{50}$ is approximately 300 to 700 ug dichlone /g of spores.

Dichlone (analytical grade) did not leach in a modified silty clay loam soil, but no predictions can be made for the soils due to a lack of test data.

Dichlone was not detected in any cropland or noncropland soil samples taken in 43 and 11 states, respectively, These samples included sites having received dichlone applications at 2.2 or 1.8 lb ai/A.

In summary, although there are too few data to form a comprehensive profile of the fate of dichlone in the environment, the information available suggest that, under some conditions, dichlone may be rapidly hydrolyzed and/or metabolized. In addition, dichlone is injurious to a diverse group of microorganisms.

## Use Profile

Dichlone is a fungicide/herbicide registered for the control of 1) various plant diseases on selected agricultural crops and ornamentals,and 2) certain bloom producing blue-green algae in swimming pools, recreational lakes and farm ponds (see Table 3 on the following page).

Dichlone is formulated as a 50% active ingredient wettable powder, 2-9% active ingredient dusts, 5% and 50% active ingredient flowable concentrates, and a 1.5% active ingredient ready-to-use formulation.

The wettable powder, dust, and flowable concentrate formulation are registered for application to fruit trees, potatoes, strawberries, celery, tomatoes, and ornamentals. The ready-to-use, flowable concentrate, and wettable powder formulations are used for algae control in lakes, ponds and pools (see Table 4 for application rates, on page 42). Dichlone was registered at one time for use on cotton as an in-furrow treatment, on turf for rust control, and as a seed treatment.

Major dichlone use is in New England and the Great Lakes States, although some use is also reported in the South. Current use is limited due to phytotoxicity problems on leaves and fruit at temperatures above 85°F and reported skin irritation. Dichlone use on fruit trees is also limited in part due to alternative fungicides that are less phytotoxic.

In 1978, 143,299 pounds of dichlone (active ingredient) were imported into the U.S. for formulation. Of that, the majority of active ingredient is used in fruit production. Use on other crops, lakes, ponds, and pools is less extensive.

## Data Gaps

All registrants of dichlone products must fulfill the data requirements as summarized on pages 18 through 19. A full description of the data requirements can be found in the Proposed Guidelines for the Registration of pesticides in the United States, 43 FR 29696, July 10, 1978.

## Table 3

### Use Patterns

| Site | Pest |
|---|---|
| Apples | Scab<br>Bitter rot<br>Black rot (frogeye leaf spot) |
| Cherries | Brown rot<br>Cherry leaf spot |
| Peaches | Brown rot<br>Leaf curl<br>Coryneum blight (California blight) |
| Plums & Prunes | Brown rot<br>Prune russett scab |
| Strawberries | Botrytis blight (gray mold) |
| Beans | Anthracnose |
| Celery | Early blight,<br>Late blight |
| Tomatoes | Botrytis blight (gray mold), Early blight, Late blight, Phoma stem rot |
| Potatoes | Late blight |
| Rose | Black spot |
| Azaleas | Petal blight |
| Aquatic Areas | Blue-green algae |

## Table 4

### Registered Application Rates

| Formulation | Site | Rate |
|---|---|---|
| WP-50% | Apples | 1/4-1/2 lb/100 gal water |
| | Peaches | 1/2- 1 lb/100 gal water |
| | Cherries | 1/2-3/4 lb/100 gal water |
| | Plums & Prunes | 1/2-3/4 lb/100 gal water |
| | Tomatoes | 3/4- 1 lb/100 gal water |
| | Strawberries | 3/8 lb/100 gal water |
| | Beans | 1-1 1/2 lb/100 gal water |
| | Celery | 1/4-1/2 lb/100 gal water |
| | Ornamentals | 1/4 lb/100 gal water |
| | Lakes, Ponds | 2.2 oz/325,960 gal water |
| | Pools | 1 oz/50,000 gal water |
| Dust 2% | Apples | 35-50 lb/acre (FMC) |
| | Cherries | or |
| | Peaches | 45-60 lb/acre (Haviland) |
| | Plums & Prunes | |
| Dust 3% | Apples | 30-50 lb/acre |
| | Cherries | 30-50 lb/acre |
| | Peaches | 30-50 lb/acre |
| | Plums & Prunes | 30-40 lb/acre |
| | Beans | up to 37 lb/acre |
| | Celery | 20-25 lb/acre |
| | Tomatoes | 15-20 lb/acre |
| Dust 6% | Apples | 10-15 lb/acre (Agway) |
| | Cherries | or |
| | Peaches | 15-20 lb/acre (Haviland) |
| Dust 9% | Apples | 10-12 lb/acre |
| | Cherries | 10-12 lb/acre |
| | Peaches | 10-12 lb/acre |
| Ready-to-use 1.5% | Pools | 1 gal/60,000 gal water |
| Flowable Concentrate 50% | Apples | 3.2 oz/100gal water |
| | Peaches | 6.4-12.8 oz/100 gal |
| | Cherries | 6.4 oz/100 gal |
| | Tomatoes | 9.6-12.8 oz/100 gal |
| | Celery | 6.4 oz/100 gal |
| | Potatoes | 6.4 oz/100 gal |
| | Ornamentals | 3.2-6.4/100 gal |
| Flowable Concentrate 5% | Lakes, Ponds | 1-5 gal/1,000,000 gal water |
| Flowable Concentrate 1.5% | Pools | 1 qt/50,000 gal water |

## TOPICAL DISCUSSIONS

Corresponding to each of the Topical Discussions listed below is the number of the section in the 'Proposed Guidelines for Registering Pesticides' in the United States (43 FR 29696, July 10, 1978) which explains the minimum data that the Agency usually requires in order to adequately assess a pesticide's Environmental Fate. Also under each of the topics is a reference to the section in the 'Proposed Guidelines'.

| Category of Test | Guideline Number |
|---|---|
| Physico-Chemical Transformation | 163.62-7 |
| Metabolism (Soil, Aquatic and Microbiological) | 163.63-8 |
| Mobility | 163.62-9 |
| Field Dissipation | 163.62-10 |
| Accumulation | 163.62-11 |

## PHYSICO-CHEMICAL TRANSFORMATION 163.62-7

### Hydrolysis 163.62-7(b)

Hydrolysis data are required to support the registration of all manufacturing-use products regardless of the intended end uses of products formulated from the manufacturing-use product.

One study was reviewed and provides preliminary data on the hydrolysis of dichlone (Burchfield, 1959, MRID 05001486). A half-life of 5 days was determined for dichlone in an M/30 phosphate buffer at pH 7. This study does not satisfy the data requirements, therefore this is a data gap.

### Photolysis 163.62-7(c)

Photodegradation studies in water are required to support the registration of all formulated products intended for terrestrial (except green-house and domestic outdoor), aquatic, terrestrial/aquatic (forest), or aquatic impact (except indirect pesticide discharges and discharges into wastewater treatment systems) uses.

Studies in soil are required to support the registration of all formulated products intended for crop uses and terrestrial/aquatic (forest) uses.

No data on the photolysis of dichlone are available. This constitutes a data gap.

## METABOLISM 163.62-8

Data on metabolism are required to determine the nature and availability of pesticide residues to rotational crops and to help in the assessment of disposal of the material and the establishment of reentry time intervals for farm workers.

### Soil 163.62-8(b,c)

Aerobic metabolism studies are required to support the registration of all formulated products intended for terrestrial uses or terrestrial/aquatic (forest) uses. Anaerobic soil metabolism studies are required to support the registration of all formulated products intended for field and vegetable crop uses.

One soil metabolism study was reviewed and provided preliminary data on the degradation of dichlone in soil (Burchfied, 1959, MRID 05001486). Under aerobic conditions only 12% of the applied dichlone (1 ppm) remained after 3 days in soil containing 17.5% water, whereas 45% remained after 3 months in soil containing 1.6% water. The soil studies did not differentiate between metabolic and hydrolytic degradative processes. This study does not satisfy the data requirements, therefore this is a data gap.

### Aquatic 163.62-8(d,e)

An aerobic aquatic metabolism laboratory study using radioisotopic techniques is required to support the registration of all formulated products intended for aquatic uses and aquatic impact uses that result in direct discharges into the aquatic environment.

An anaerobic aquatic metabolism laboratory study using radioisotopic analytical techniques is required to support the registration of all formulated products intended for aquatic, terrestrial/aquatic (forest), and aquatic impact uses that result in direct discharges into the aquatic environment.

No data on the aquatic metabolism of dichlone are available. This constitutes a data gap.

### Microbiological 163.62-8(f)

Data on the effects of microbes on pesticide degradation and the effects of pesticides on microbes are required to support the registration of all formulated products intended for the following uses: terrestrial noncrop, tree fruit/nut crop, field/vegetable crop, aquatic food crop and noncrop, terrestrial/aquatic (forest), and direct discharge aquatic impact.

### Microbiological - Effects of Microbes on Pesticides 163.62-8(f)(2)

One study was reviewed; however, no valid data on the effects of microbes on dichlone are available. This constitutes a data gap.

### Microbiological - Effects of Pesticides on Microbes 163.62-8(f)(3)

Eight studies were reviewed and five are considered valid.

Zweig *et* al. (1968, MRID 05001627), showed that, at a concentration of $3 \times 10^{-5}$ M, dichlone completely inhibits oxygen evolution and chlorophyll production and markedly decreases cell numbers of the alga *Chlorella pyrenoidosa* at 48 hours of exposure. *Chlorella* cultures were completely nonviable at 65 and 90 hours of exposure.

Saxena et al. (1973, MRID 05001698), investigated the effect of dichlone on bacterial photosynthesis in *Rhodospirillum rubrum* (a photosynthetic nonsulfur bacterium) and postulated that dichlone causes irreversible damage to some primary photosynthetic reactions in chromatophores. The light-dependent growth of photoautotrophic and photoheterotrophic cultures of *R. rubrum* was inhibited at 1 uM, whereas heterotrophic growth was temporarily inhibited by dichlone at levels greater than 3 uM.

The effects of dichlone on nitrogen cycle processes have been studied by measuring nitrate evolution and by investigating dichlone's effect on soil nitrification and on the symbiotic relationship of host plants and nitrogen-fixing bacteria. Wilson (1954, MRID 05001641) observed that soil nitrification, as measured by nitrate evolution, was inhibited 38% by dichlone at 95 ppm. Kecskes and Vincent (1969, MRID 05004330) demonstrated that dichlone (0.6 g/kg) applied to vetch (*Vicia sativa* ) seeds inhibited the development of taproot nodules and stimulated the development of lateral root nodules in both soil and sand. Total nodule formation, however, decreased by 12% compared with that in controls.

Neely et al. (1973, MRID 05001654) reported that dichlone at concentrations between 0.5 and 0.9 g/ml temporarily inhibited *Escherichia coli* growth. Sulfhydryl-containing compounds (cysteine, homocysteine, and reduced glutathione) prevented the inhibitory effects of dichlone when added with the dichlone and slightly shortened the growth recovery time lag when added 30 minutes after dichlone treatment. This study contains useful information on the effects of dichlone on microorganisms, although *E. coli* is not a representative soil organism.

A study by Le Toureau (1957, MRID 05001519) indicated that dichlone at a concentration of $10^{-6}$M delayed growth of *Verticillium albo-atrum* (a fungus) for over 12 days and inhibited the growth about 70%. In a study conducted by Miller and McCallan (1955, MRID 05001657), dichlone was shown to inhibit germination of fungus spores. The chart below shows the dose of dichlone required to inhibit germination at the 50% level. The dose is in micrograms of dichlone per gram of spores.

| Species | $ED_0$ |
|---|---|
| *Neurospora sitophila* | 560 ug/g spores |
| *Monilinia fructicola* | 385 |
| *Alternaria oleracea* | 400 |
| *Rhizopus nigricans* | 680 |
| *Myrothecium verrucaria* | no effect at 1400 ug/g spores |

Table 5 summarizes the effects of dichlone on selected microbes. These studies partially fulfill the data requirements by providing information on the effect of dichlone on nitrification.

## Table 5

## Effects of Dichlone on Microbes

| Range of dichlone concentrations (active ingredient) | Species | Observations | Reference |
|---|---|---|---|
| 19-95 ppm | unspecified | Nitrification, as measured by $NO_3$ evolution, was inhibited at 95 ppm but not at 19 ppm. | Wilson (1954) MRID 05001641 |
| 0.6 g/kg seed | *Rhizobium* spp. | Vetch taproot nodules were inhibited; lateral root nodules were stimulated. Only 88% of plants formed nodules (compared with 100% of controls). | Kecskes and Vincent (1969 MRID 05004330 |
| $3.5 \times 10^{-5}$M | *Chlorella pyrenoidosa* | $O_2$ evolution decreased about 50% within 60 minutes. After 48 hours, $O_2$ evolution decreased to zero. Cell viability was destroyed within 65-90 hours. | Zweig et al. (1968) MRID 05001627 |
| -150 uM | *Rhodospirillum rubrum* | Photoautotrophic and photoheterotrophic growth were inhibited at 1 uM or more. | Saxena et al. (1973) MRID 05001698 |
| 0.5 - 0.9 ug/ml | *Escherichia coli* | Growth was inhibited; however, recovery to near normal growth was observed following inhibition. | Neely et al. (1973) MRID 05001654 |

All studies specified in Section 163.62-8(f)(3), except those on nitrification, are required for dichlone. It is also recommended, per Section 163.62-3, that sufficient data be acquired on the effects of dichlone on aquatic nontarget microorganisms (viz., the eukaryotic algae). This recommendation is made because the available data suggest that dichlone may have an adverse impact on these microorganisms; which constitute the majority of the primary producers in aquatic environments.

## Activated Sludge 163.62-8(g)

A laboratory study of the effects of pesticides on the wastewater treatment process is required to support the registration of all manufacturing-use products and all formulated products that are indirectly discharged into wastewater systems.

No data on the activated sludge metabolism of dichlone are available. This constitutes a data gap.

## MOBILITY 163.62-9

Data on mobility are required to determine pesticide residue movement in the environment.

## Leaching 163.62-9(b)

Leaching data are required to support registration of formulated products intended for terrestrial noncrop, tree fruit/nut crop, field/vegetable crop, and terrestrial/aquatic (forest) uses.

Helling et al.(1974, MRID 05001190) found that dichlone was immobile on soil TLC plates coated with a modified (sieved to <250 um) Hagerstown silty clayloam. This study showed $R_f$ values ranging from 0.01 to 0.03 with a mean $R_f$ of 0.02.

Alone, this study is insufficient to draw any conclusions regarding dichlone's leaching potential. This constitutes a data gap.

## Volatility 163.62-9(c)

Laboratory volatility studies using nonradioisotopic analytical techniques are required to support the registration of all formulated products intended for greenhouse use.

Volatility data are only required for pesticides used in greenhouses. Therefore, data are not required on the volatility of dichlone because no formulated products of dichlone have yet been proposed for greenhouse use.

## Adsorption/Desorption 163.62-9(d)

A laboratory study using radioisotopic or nonradioisotopic analytical techniques is required to support the registration of all formulated products intended for all terrestrial uses, terrestrial/aquatic (forest) uses, aquatic uses, and aquatic impact uses (if the pesticides are discharged directly into the aquatic environment).

No data on the adsorption/desorption of dichlone are available. This constitutes a data gap.

## Water Dispersal 163.62-9(e)

A field study tailored to one or more representative sites is required to support the registration of all formulated products intended for aquatic uses and aquatic impact uses (if the pesticides are discharged directly into aquatic sites).

No data on the water dispersal of dichlone are available. This constitutes a data gap.

## FIELD DISSIPATION 163.62-10

A field dissipation study under actual use conditions is required to support the registration of all formulated products intended for terrestrial (except greenhouse) uses, aquatic uses, and terrestrial/aquatic (forest) uses.

### Terrestrial 163.62-10(b)

Terrestrial field dissipation studies using the formulated product are required to support the registration of each pesticide formulation intended for all terrestrial (except greenhouse) uses, terrestrial/aquatic (forest) uses, and aquatic food crop uses.

Two studies were reviewed and one was considered valid. In a monitoring study conducted by Wiersma et al. (1972, MRID 05004938) dichlone was not detected in any sample of cropland soils sampled in 43 states, and noncropland soils sampled in 11 states.

These data alone are insufficient to assess the rate or the impact of the dissipation of dichlone in the field. This constitutes a data gap.

### Aquatic 163.62-10(c)

Aquatic field dissipation studies using the formulated product are required to support the registration of each pesticide formulation intended for all aquatic uses, terrestrial/aquatic (forest) uses, and aquatic impact uses (if the pesticides are discharged directly into the aquatic environment).

No data on the aquatic dissipation of dichlone are available. This constitutes a data gap.

### Terrestrial/Aquatic (Forest) 163.62-10(d)

A special ecosystem residue study is needed to support the registration of each pesticide formulation intended for terrestrial/aquatic (forest) uses.

No data on the terrestrial/aquatic dissipation of dichlone are required because the use pattern indicates that introduction into the forest environment would not occur.

### Aquatic Impact Uses 163.62-10(e)

Aquatic impact use studies are required to support the registration of all formulated products that will be directly or indirectly discharged into the aquatic environment or are intended for use in wastewater treatment systems.

No data on the aquatic impact of dichlone are available. This constitutes a data gap.

## ACCUMULATION 163.62-11

Data on accumulation are required to determine accumulation in food chains.

### Rotational Crops 163.62-11(b)

Rotational crop studies are required to support the registration of all formulated products intended for field/vegetable and aquatic food crop uses.

No data on the accumulation of dichlone in rotational crops are available. This constitutes a data gap.

### Irrigated Crops 163.62-11(c)

A crop residue study under actual field use conditions is required to support the registration of all formulated products intended for aquatic food or aquatic noncrop uses, or for use in holding ponds or effluent and other discharged sources used to irrigate crops. No data on the accumulation of dichlone in irrigated crops are available. This constitutes a data gap.

### Fish 163.62-11(d)

This laboratory study employing radioisotopic or nonradioisotopic analytical techniques is required to support the registration of all formulated products intended for terrestrial noncrop, tree fruit/nut crop, and field/vegetable crop uses; aquatic food crop and noncrop uses; terrestrial/aquatic (forest) use; and aquatic impact (direct discharge) uses.

No data on the accumulation of dichlone in fish are available. This constitutes a data gap.

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# Chapter V

## Toxicology Chapter

DISCIPLINARY REVIEW

Toxicology Profile
Data Requirements and Data Gaps
Required Labeling

### Toxicology Profile

### Technical Dichlone

Insufficient data were reported to support an assessment of technical dichlone's acute toxicity. The low acute oral $LD_{50}$ in rats (1.63 g/kg) indicates a potentially low acute oral toxicity in humans. No data were reported for acute dermal and acute inhalation toxicity.

Insufficient data were available to support an assessment of technical dichlone's irritation and sensitization potential. An inadequate eye irritation study conducted on rabbits suggests that technical dichlone is moderately irritating to the eye. An inadequate dermal sensitization conducted on guinea pigs suggests no allergic response.

Insufficient data were available for the assessment of subchronic and chronic toxicity of technical dichlone. The oncogenic, reproduction, chronic feeding, and mutagenicity studies submitted were inadequate due to improper testing protocols and/or insufficient data reporting. No data were available for teratology and animal metabolism.

### Dichlone Formulations

No tests were reported for the wettable powder, dust, flowable concentrate, and ready-to-use formulations to assess the acute oral, dermal, and inhalational toxicities, primary eye and dermal irritation, and dermal sensitization.

### Data Requirements and Data Gaps

All registrants of dichlone products must fulfill the data requirements as summarized on pages 23 through 25. A full description of the data requirements can be found in the Proposed Guidelines for the Registration of pesticides in the United States, 43 FR 37336, August 22, 1978.

### Required Labeling

### Acute Oral Toxicity

The acute oral toxicity for technical dichlone in rats is 1.63 g/kg, which corresponds to Toxicity Category III. Precautionary statements for the acute oral toxicity is: "Harmful if swallowed".

Labels may be changed after submission of acute toxicity data.

### Primary Eye Irritation

One test has shown that dichlone is a moderate eye irritant. This test had some inadequacies that will necessitate more testing. At this time, however, a precautionary statement, "Eye Irritant" is required on the label.

### Primary Dermal Irritation

One test has shown that dichlone is a moderate skin irritant. This test had some inadequacies that will necessitate more testing. At this time, however, a precautionary statement, "Skin irritation is possible, especialy at elevated temperatures" is required on the label.

### Dichlone Formulations

No acute oral, dermal, or inhalation toxicity, primary eye or primary skin irritation, or skin sensitization tests are available. Therefore, no additional labeling is required at this time.

## TOPICAL DISCUSSIONS

Corresponding to each of the Topical Discussions listed below is the number of the section(s) in the 'Proposed Guidelines' of 43 FR 37336, August 22, 1978, which explain(s) the minimum data that the Agency usually requires in order to adequately assess a pesticide's toxicology. Also under each of the topics is a reference to the section in the 'Proposed Guidelines'.

| Acute Testing | Guideline Section |
|---|---|
| Acute Oral Toxicity | 163.81-1 |
| Acute Dermal Toxicity | 163.81-2 |
| Acute Inhalation Toxicity | 163.81-3 |
| Primary Eye Irritation | 163.81-4 |
| Primary Dermal Irritation | 163.81-5 |
| Dermal Sensitization | 163.81-6 |
| Acute Delayed Neurotoxicity | 163.81-7 |
| Subchronic Testing | |
| Subchronic Oral Toxicity | 163.82-1 |
| Subchronic 21-Day Dermal Toxicity | 163.82-2 |
| Subchronic 90-Day Dermal Toxicity | 163.82-3 |
| Subchronic Inhalation Toxicity | 163.82-4 |
| Subchronic Neurotoxicity | 163.82-5 |
| Chronic Testing | |
| Chronic Feeding Studies | 163.83-1 |
| Oncogenicity | 163.83-2 |
| Teratogenicity | 163.83-3 |
| Reproduction | 163.83-4 |
| Mutagenicity | 163.84-(1-4) |
| Metabolism | 163.85-1 |

## ACUTE TESTING

### ACUTE ORAL TOXICITY (163.81-1)

The minimum testing needed on acute oral toxicity is one test with the laboratory rat using the technical chemical and each manufacturing-use and formulated product.

#### Technical

The acute oral $LD_{50}$ of dichlone (Phygon of unspecified purity, as a suspension in water containing 2% Tween 80) in the rat was 1.63 g/kg in one test and 1.32 g/kg in a second test conducted in the same laboratory (FRL,1952a, MRID 00001521). The presence of 30 and 598 ppm of lead in the samples used, although undesirable, was characteristic of the technical product in use at that time and would not have materially affected these acute toxicity measurements. Signs of intoxication included sluggishness, depression, gastrointestinal irritation, and temporary weight loss. At autopsy, some treated animals showed cardiac and pulmonary congestion, gastric hemorrhage, and intestinal hemorrhage.

This test in rats is adequate to fulfill data requirements for an acute oral test. Based on these data, dichlone can be placed in toxicity Category III, corresponding to a low acute oral hazard.
In guinea pigs, the $LD_{50}$ for a sample of dichlone (Phygon) containing 30 ppm of lead was 0.32 g/kg. (FRL 1952a, MRID 00001521). Signs of intoxication included depression and stupor. Based on lethal dose values, the guinea pig is more sensitive than the rat to large doses of dichlone (Phygon). Testing in species other than the rat is not required to fulfill data requirements.

### Dichlone Formulations

No tests were reported for the wettable powder, dust, flowable concentrate, and ready-to-use formulations to assess the acute oral toxicity of dichlone. Testing is required for all the mentioned formulations.

## ACUTE DERMAL TOXICITY (163.81-2)

The minimum testing needed on acute dermal toxicity is one test, on the rat or albino rabbit, on each technical, manufacturing-use and formulated product.

### Technical

No tests of acute dermal toxicity are available on technical dichlone. Testing is required.

### Dichlone Formulations

No tests were reported for the wettable powder, dust, flowable concentrate, and ready-to-use formulations to assess the acute dermal toxicity. Testing is required for all the mentioned formulations.

## ACUTE INHALATION TOXICITY (163.81-3)

The minimum testing required on acute inhalation toxicity is one test, preferably on the rat, for each manufacturing-use product and each formulated product that is a gas, that produces a respirable vapor, or that is composed of 20% or more of particles not larger than 10 microns in diameter.

### Technical

No tests were reported on the acute inhalation of technical dichlone. Testing is required.

### Dichlone Formulations

No tests were reported for the wettable powder, dust, flowable concentrate, and ready-to-use formulations to assess the acute inhalation toxicity. Testing is required for all the mentioned formulations.

## PRIMARY EYE IRRITATION (163.81-4)

The minimum testing needed to evaluate eye irritation potential is one test on the albino rabbit on each technical, manufacturing-use and formulated product.

### Technical

Application of one drop of 5% suspension of Phygon in physiological saline to the eyes of five rabbits resulted in moderate irritation of the conjunctiva and mild irritation of the cornea; these effects were reversible within two days (FRL, 1952b, MRID 00001522). Although this study indicates a moderate eye irritation hazard, the test must be repeated using an adequate number of rabbits to fulfill data requirements.

### Dichlone Formulations

No tests were reported for the wettable powder, dust, flowable concentrate, and ready-to-use formulations to assess the primary eye irritation. Testing is required for all the mentioned formulations.

## PRIMARY DERMAL IRRITATION (163.81-5)

The minimum testing needed to evaluate dermal irritation potential is one test on a mammal, preferably on the albino rabbit, for each technical, manufacturing-use and formulated product.

### Technical

Application of a 20% suspension of Phygon to intact and abraded rabbit skin (for 6 hours/day on days 1-5 and 15-20) resulted in slight dermal irritation; no irritation was observed 3-4 days after the last application (FRL, 1952b, MRID 00001522). Although this study indicates only a slight dermal irritation hazard for dichlone, this test must be repeated using a measured amount of test substance over a single 24-hour exposure period to fulfill data requirements. Additional testing is required.

### Dichlone Formulations

No tests were reported for the wettable powder, dust, flowable concentrate, and ready-to-use formulations to assess the primary dermal irritation. Testing is required for all the listed formulations.

## DERMAL SENSITIZATION (163.81-6)

The minimum testing required to assess dermal sensitization is an intradermal test on one mammalian species, preferably the guinea pig, for each manufacturing-use and formulated product.

### Technical

No evidence of an allergic response was observed following a dermal sensitization test on a 0.1% suspension of Phygon in six guinea pigs (FRL, 1952b, MRID 00001522). However, to adequately assess sensitization potential, this test must be repeated using a larger number of animals. Additional testing is required.

## Formulations

No tests are available for wettable powder formulations, dust formulations, flowable concentrate formulations and ready-to-use formulations to assess the dermal sensitization potential. Testing is required for all the mentioned formulations.

## ACUTE DELAYED NEUROTOXICITY (163.81-7)

The minimum data requirements for acute delayed neurotoxicity is one test for the technical formulation, using the adult hen.

The acute delayed neurotoxicity data are required if the active ingredient, or any of its metabolites, degradation products, or impurities cause acetyl cholinesterase depression or are structurally related to a substance that induces delayed neurotoxicity.

An acute delayed neurotoxicity study is not required on dichlone because it is not expected to cause acetyl cholinesterase depression nor is it related to a substance that induces delayed neuropathy.

## SUBCHRONIC TESTING

## SUBCHRONIC ORAL TOXICITY (163.82-1)

The minimum data requirements for subchronic toxicity are one test for the technical formulation in two mammalian species, preferably using the rat and dog.

The subchronic rat and dog studies are required. The rat subchronic feeding study is required to lay the foundation for the rat two year feeding study. It provides us with information on possible toxicity within six months where as the chronic study will take years to provide such data. Since only one chronic feeding study is required (in rats), there is no substitute for the second species, a subchronic feeding study on the dog.

In a limited subchronic oral test, rats were given 0, 500, 1,580 or 5,000 ppm of Phygon in the diet for 12 weeks (FRL, 1952c, MRID 00001523). The test sample contained 30 to 600 ppm of lead. Growth depression, probably the result of the unpalatability of the diet, was observed throughout the study at the highest dose (5,000 ppm) and during the first four weeks at 1,580 ppm. No significant changes were observed in clinical chemistry parameters. Animals were bred during the last month of the study, necropsies were not performed (except on one animal that died during the study), and the test sample was contaminated with lead; therefore, this study cannot be considered an adequate subchronic test.

No adequate tests of dichlone in dogs are available. No reliable conclusions can be drawn from a study in dogs given 500 or 1,580 ppm of Phygon in the diet for one year (FRL, 1952d, MRID 00001524) because too few animals were tested (three dogs per dose), the Phygon samples were contaminated with high levels of lead (30 or 600 ppm), and three dogs became pregnant during the test. Additional subchronic oral testing is required.

## SUBCHRONIC 21-DAY DERMAL TOXICITY (163.82-2)

The minimum requirement to assess subchronic 21-day dermal toxicity is one study in the rabbit on the technical product.

This test is not required for dichlone because data from the subchronic 90-day dermal toxicity study are required.

## SUBCHRONIC 90 DAY DERMAL TOXICITY (163.82-3)

The minimum data requirement for subchronic 90-day dermal toxicity is one test for the technical formulation, preferably using the albino rabbit.

A subchronic 90-day dermal toxicity test is required on dichlone because it is unintentionally applied to skin when it is applied as an agricultural fungicide and as a herbicide for the control of algae in swimming pools.

## SUBCHRONIC INHALATION TOXICITY (163.82-4)

The minimum data requirement for subchronic inhalation toxicity is one test for the technical formulation, preferably using the albino rabbit.

A subchronic inhalation study will be required if the pesticidal uses result in repeated exposure at a concentration that is likely to cause a toxic effect as determnined by the acute inhalation and other testing.

## SUBCHRONIC NEUROTOXICITY (162.82-5)

The minimum data requirements for subchronic neurotoxicity are one test in the chicken for the technical formulation or compounds which gave positive results on the acute neurotoxicity test. The minimum requirement for subchronic neurotoxicity is one test for the technical formulation on compounds which caused irreversible neurological toxicity in a mammalian species and the test must be performed on that species.

A subchronic neurotoxicity study of dichlone is not required because an acute neurotoxicity study was not required. At present there is no evidence to require a mammalian study.

## CHRONIC TESTING

## CHRONIC FEEDING (163.83-1)

The minimum requirement for chronic feeding study is testing in one mammalian species, preferably the laboratory rat.

A chronic feeding study is required for dichlone because certain uses require tolerances.

A 2-year feeding study on the rat was conducted on Phygon at 0, 500, 1,580, and 5,000 ppm; the sample tested was contaminated with 600 ppm lead (FRL,1952c, MRID 00001523). Growth rate was depressed at the highest dose. The animals used were part of a reproduction study (discussed in the section on reproduction in this review), and the total number of test animals was too low; therefore, this cannot be considered an adequate chronic test. Testing must be repeated in the rat utilizing, if possible, lead-free test material.

## ONCOGENICITY (163.82-2)

The minimum requirement for oncogenicity, is testing in two mammalian species, preferably the rat and mouse, using the technical formulation.

This study is required for dichlone because certain of its uses require a tolerance. No oncogenicity tests are available on dichlone that meet currently accepted protocols. No oncogenic potential was noted in mice given dichlone orally for 18 months (21 days by gavage at 10 mg/kg/day, then in feed at 30 ppm) or by a single injection (21.5 mg/kg) (Innes et al., 1969, MRID 05004401 and Bionetics Research Laboratories,1968, MRID 05010016). However, because of the large number of shortcomings in the design and conduct of these tests, results were inconclusive. Additional testing is required in the rat and mouse.

## TERATOGENICITY (163.83-3)

The minimum requirement for teratogenicity is testing in two mammalian species using technical formulations.

This study is required for dichlone because certain of its end-uses require a tolerance.

No teratogenicity studies are available for dichlone. Testing in two mammalian species is required.

## REPRODUCTION (163.83-4)

The minimum requirement for reproduction is testing in one mammalian species, preferably the laboratory rat, using the technical formulation and lasting for two generations.

This study is required for dichlone because certain of its uses require a tolerance.

### Technical

Phygon (exact dichlone content unspecified) with lead contamination of 600 ppm was administered in the diet at concentrations of 0, 500, 1,580, or 5,000 ppm to groups of rats (10 male and 10 female rats) from about 25 days of age (FRL, 1952c, MRID 00001523). There was no indication of impaired ability to conceive and bear litters in any dose group. However, throughout all the matings of the $F_0$ generation and the two matings of the $F_1$ and $F_2$ generations, a pattern was established in which the animals in the high-dose group had lower weights (at birth, at weaning, and at mating) and produced smaller litters with poorer survival to weaning than did the control at the two lower dose groups. The interpretation of these effects is made difficult by the fact that apparent unpalatability of the high-dose diet led to reduced food consumption. The growth depression in the adults might be attributable to this. The fetal effects might also be attributable indirectly to reduced food consumption because of reduced maternal ability to provide adequate nutrition.

The group sizes were not sufficiently large, particularly at the high-dose level, and histopathological examinations were not performed on the $F_1$ adults or on $F_1$ and $F_2$ weanlings. Therefore, this study can only give supplementary information on the reproductive effects of Phygon. Additional testing in the laboratory rat is required.

MUTAGENICITY (163.84-1 through-4)

The following studies represent only the minimum requirements for data on the potential heritable effects of dichlone.

1. A mammalian in-vitro point mutation test.
2. A sensitive sub-mammalian point mutation test. (Bacteria, fungi, insect).
3. A primary DNA damage test (i.e. sister chromatid exchange or unscheduled DNA synthesis).
4. A mammalian in-vitro cytogenetics test. If this test suggests a positive result, a dominant lethal or heritable translocation test may be required.

After the results of these test systems and other toxicology disciplines have been considered, additional testing may be required to further characterize or quantify the potential genetic risks.

Although the Agency's mutagenic testing requirements are not final, the standards for these tests should be based on the priciples set forth therein (43 FR 37388, August 22, 1978). Protocols and choices of test systems should be accompanied by a scientific rationale. Substitutions of test systems for those listed above will be considered after discussion with the Agency.

The requirements should be considered an interim guide and not final Agency policy. However, the Agency does consider the above testing scheme to be a reasonable minimum requirement.

Mutagenicity testing is required for dichlone because certain of its uses require a tolerance. A test for gene mutations in Salmonella using dichlone (Anderson et al., 1972, MRID 05001460) was inadequate because of several deficiencies in reporting (e.g., criteria for judging results positive or negative were not stated) and the fact that no metabolic activation system was used.

METABOLISM IN LABORATORY ANIMALS (163.85-1)

The minimum data requirements for metabolism require testing in the laboratory rat with analytically pure compound of the active ingredient to determine absorption, distribution, metabolism and excretion of the compound.

A metabolism study is required for dichlone because the product requires a chronic feeding study and an oncogenicity study. Testing is required.

## CLINICAL TRIALS

No clinical studies in humans have been conducted using dichlone.

## EMERGENCY TREATMENT

No information on the prevention and treatment of dichlone intoxication is available. This information is required.

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## Chapter VI

## Residue Chemistry Chapter

DISCIPLINARY REVIEW

Residue Chemistry Profile
Generic Data Gaps
Required Labeling

### Residue Chemistry Profile

Dichlone is marketed in the USA as a herbicide (plant regulator) and as a fungicide. The metabolism and/or pathway of degradation of dichlone when applied to aquatic areas and agricultural crops has not been detailed. There is some indication in the literature that dichlone in solution under ordinary laboratory conditions decreases in concentration with time. When similar solutions of dichlone were exposed to sunlight, conversion products were noted. The major conversion product was determined to be 2-chloro-3 phenyl-1,4-naphthoquinone. No metabolism or breakdown patterns of dichlone were identified in plants and animals. Additional studies should be submitted exhibiting the nature of the major residues when dichlone is applied to plants and digested by animals.

Assuming that dichlone *per se* is the only residue to be determined, adequate analytical methods are available for analysis in agricultural commodities such as apples, beans, celery, cherries, peaches, plums (fresh prunes), tomatoes and strawberries.

Residue studies show the use of certain application rates of dichlone on apples, beans, celery, cherries, peaches, plums (fresh prunes), tomatoes and strawberries. These studies show that the residues of dichlone *per se*, resulting from these certain applications, do not exceed the established pesticide tolerances for the above commodities. However, the residue studies do not reflect residues which could result from the latest registered uses including the maximum proposed rates. Accordingly, additional residue studies have to be submitted to justify the registered uses and established tolerances.

Because some by-products of treated crops, such as apple pomace, bean vines, forage and hay and tomato pulp are fed to cattle, horses, pigs and other farm animals, residue studies should be submitted reflecting the extent to which residues of these commodities are fed to food animals. These include residue studies on cover crops in fruit orchards that are being grazed by food animals. If the residue studies indicate that food animals are fed agricultural commodities carrying residues, then animal feeding studies are needed to reflect the degree of transfer of residues to the meat and milk of these animals.

There are no records of regulatory incidents involving the enforcement of dichlone tolerances.

## Generic Data Gaps

Metabolism and degradation studies indicating the nature of the residue in plants and animals caused by an application or by the feeding of dichlone have not been reported.

If the final resulting residue is identified as being different from dichlone *per se*, analytical methodology is needed to identify and quantify these residues on treated crops, their by-products and incidental commodities (cover crops in orchards).

Residue data have to be submitted reflecting dichlone residues as a result of the maximum registered usage rate, in samples taken on certain dates after the application, in order to establish a time lapse degradation pattern for the residues. Residue studies reflecting dormant applications in combination with other applications to apple and peach trees are required.

Residue processing studies have to be submitted showing the amount of dichlone residue in apple pomace and tomato pulp. If a concentration of residue in apple pomace and tomato pulp is indicated to the extent that the residue level exceeds that of the tolerance level established for the raw agricultural commodity, a Food Additive tolerance for the apple pomace and the tomato pulp will be required.

Residue studies reflecting the persistence of dichlone residues in water resulting from the proposed uses are essential in determining whether appropriate tolerances for potable water, fish, irrigated crops, etc. will have to be established. The Office of Pesticide Programs (OPP) will transfer scientific information about dichlone to EPA's Office of Drinking Water (ODW) so that ODW may consider monitoring for dichlone residues in water.

Animal feeding studies have to be submitted to establish the extent of transfer of residues to meat and milk of animals as a result of the maximum registered uses.

All residue studies should be supported by storage stability studies if samples were held in storage before analysis. Handling history of the samples should accompany the residue studies.

## Required Labeling

Certain label restrictions will depend on the content of available data to be submitted. For instance, a lack of residue data on cover crops could be handled through a label restriction like "do not graze livestock on cover crops in treated orchards."

Since there are registered uses which direct the application of dichlone to lakes (recreational areas) and farm ponds, there is a reasonable expectation that dichlone may be carried over and accumulated in potable water, fish, irrigated crops and livestock. In the later case, residues may result in meat and milk.

Accordingly, to prevent human exposure by the drinking of treated water, the use of treated water for livestock, the taking of fish from treated water, the use of treated water for irrigational purposes, and the drainage of treated water into flowing streams, appropriate tolerances instead of label restrictions may be necessary for the affected commodities.

There is an indication that the presently maximum registered application rates are different from those in effect when the tolerances were established. All current and future label use directions should be consistent with the restrictions specified in the Use Restriction Section of the Topical Discussions for each crop.

Accordingly, the required labeling will depend on the fulfillment of the generic data gaps.

## TOPICAL DISCUSSIONS

This Registration Standard for dichlone is concerned with formulations containing a single active ingredient. Conclusions or implications derived from data on single active ingredient formulations do not necessarily apply to multiple active ingredient formulations.

## USE PATTERNS

Dichlone is marketed in the USA as a fungicide and a herbicide. As a fungicide, dichlone is applied to various agricultural commodities and ornamental plants to control a number of plant diseases. As a herbicide, dichlone is applied to aquatic environments such as lakes, ponds, and swimming pools to control blue-green algae.

Dichlone is formulated as a flowable concentrate, a ready-to-use product, a wettable powder and a dust. The flowable concentrate is formulated with 50%, 5%, 4.9% and 1.5% active ingredient. The ready-to-use product formulation contains the active ingredient at 1.5%.

The wettable powder is formulated with 50% active ingredient; the dichlone dust with 9%, 6%, 3% and 2% active ingredient.

When the above formulations are being used, the following should be observed: "Dichlone is toxic to fish, bees, pets and wildlife. Therefore, keep out of lakes, streams, or ponds unless they are the specific site being treated. Do not contaminate water by cleaning of equipment or disposal of waste. Keep away from domestic animals and foodstuffs. Do not use in sprays containing lime, calcium arsenate, or dinitro compounds, oil or emulsifiable concentrates. Do not apply when runoff is likely to occur, or within 10 to 14 days of an oil spray. Do not apply prior to or during periods of excessively high (85°F) temperatures, nor when weather conditions favor drift of dust from treated crop areas."

### Aquatic Uses

When dichlone is applied to aquatic areas for the treatment of blue-green algae, the following use-limitations are required on the labels:

### Lakes and ponds

Flowable concentrate: Use 0.333 gallons of 5% dichlone concentrate per acre-foot of water (spray) about every three weeks.

Wettable powder: Use 1.1 oz. dichlone/acre - foot of water every two or three days.

### Swimming Pools

Flowable concentrate: Use 1 qt. 1.5% dichlone concentrate/50,000 gallons of water every week or less.

Wettable powder: Use 0.5 oz. dichlone/50,000 gallons of water every week to every two weeks.

Ready-to-use product: Use 0.5 gal. 1.5% dichlone formulation/30,00 gallons of water every two weeks.

NOTE: Always apply when water temperature is above 55°F.

Agricultural and Ornamental Uses

When dichlone is used as a fungicide, it is applied to various agricultural crops and ornamentals for the prevention or treatment of various plant diseases. The treatment may consist of a single application or a series of applications with each one being applied at a designated stage of bud, blossom, fruit and/or leaf development.

Ornamental Use

The recommended rates of application for ornamentals are: On roses use a multiple foliar spray at 0.125 lb. a.i./100 gal. every seven days after leaves first appear.

On azaleas, use a multiple foliar spray at 0.25 lb. a.i./100 gallons every two days for the treatment of petal blight.

Agricultural Uses

The proposed maximum rates of application of dichlone to agricultural commodities will be described in the section covering the residues of dichlone on the agricultural crops.

METABOLISM (in plants and animals)

No information on the fate of dichlone has ever been submitted by manufacturers or interested parties. An article by White et al. (1969, MRID 05001410) showed that standard solutions of dichlone decreased in concentration with time under ordinary laboratory conditions. There was a simultaneous increase in the concentration of degradation and/or conversion products. The major conversion product was determined to be 2-chloro-3-phenyl-1,4-naphthoquinone. This same conversion product was noted after a solution of dichlone was exposed to sunlight.

A study by Owens (1969, MRID 05002878), shows that dichlone, when reacted (under laboratory conditions) with glutathione, produced an indeterminable product which was assumed to be a mixture of mono- and di-substituted products.

This limited information gives some indication of the possible fate of dichlone. However, for registration purposes, more extensive studies, preferably some studies using radio-tracer techniques, should be submitted. Presently, the fate of dichlone residue in plants and animals is not adequately explained. This is a data gap.

ANALYTICAL METHODOLOGY

Until the path of metabolism and degradation of dichlone residues in plants and animals can be clarified, it is assumed that the residue of concern is dichlone *per se*. Accordingly, the methods at hand for the analysis of dichlone will determine dichlone per se (the parent compound). The accepted method for the determination of dichlone in agricultural crops, i.e., peaches, apples, strawberries, stringbeans and tomatoes, is published in the Pesticide Analytical Manual, Volume II. The principles of the above method are explained in Burchfield (1948, MRID 05001359) and Bornmann (1957, MRID 05002988). This method was subjected to thorough analytical research for accuracy and sensitivity. According to this method, vegetables are stripped with benzene, the extract cleaned up on an activated Florisil column and eluted with 1% acetone in benzene. Any residues of dichlone which are present will react with dimethylamine to produce an intense orange color. The dimethylamine reaction product is then read spectrophotometrically at 495 millimicrons and compared with previously established dichlone-standard readings.

Additional work proving the adequacy of the above method is shown in Miller (1965, MRID 05001416) and Lane (1958, MRID 05001408). The first study reports results on 10 collaborators who fortified peach-, tomato-, and strawberry samples with dichlone in the 0.5-4.0 ppm range. The method sensitivity was found to be 0.25 ppm. Recoveries of dichlone residues in peaches were 78-112%; in tomatoes, 88-110% and in strawberries, 80-105%.

In Lane (1958, MRID 05001408), practically the same method was tried out on peaches, apples, strawberries, stringbeans and tomatoes. The fortification levels of dichlone ranged from 0.4 ppm to 1.0 ppm resulting in recoveries of 85% to 101%, averaging 91% for 18 crops. These data are very consistent and support the adequacy of the method.

In Zweig (1972, MRID 05001656) the author discusses a gas chromatographic method for the analysis of dichlone residues in or on agricultural crops. Since no particulars as to the operation of the method are reported, no opinion can be offered as to its adequacy with regard to recovery and sensitivity.

For the analysis of dichlone residues in tobacco a method is presented in Hoffman (1965, MRID 05001490) by which dichlone can be determined independently of other chemicals applied, such as maleic hydrazide. One option is to extract the crop sample with benzene and water, then draw off the water, concentrate the benzene and cleanup the benzene extract on a florisil column eluting the column with methylene chloride. Evaporate the eluate and take up dichlone residues in absolute alcohol and add triethylamine to develop a blue color. Measure the absorbance of the colored solution at 650 millimicrons. Recoveries from treated tobaccos were found in the range of 93-100%. Maleic hydrazide does not form a colored complex with triethylamine.

Another option is to extract the sample with methylene chloride, filter the extract and reduce the volume to about 1 ml. Apply the sample to a T.L.C. plate and develop the plate in 1:1 chloroform: trichloroethylene. Determine the dichlone residue band under a long-wave ultraviolet light source with a dichlone reference spot run on the same plate. Scrape off the band representing the dichlone residue and extract with methylene chloride by mixing with a stirring rod. Filter and extract two more times with methylene chloride. Combine the methylene chloride extracts and reduce volume. Spot an amount representing a known quantity of sample and also spot standard amounts of dichlone. Develop the plate as before. When the plate is dry, spray with diethylamine and estimate the amount of dichlone by comparing sample spot with standard spots. This latter method offers a simple technique for the fast screening of samples. Quantitatively, the spectrophotometric procedure is far better for determining dichlone residues in tobaccos.

The above detailed spectrophotometric method was researched in regard to the use of dimethylamine, diethylamine and triethylamine in color development for the reaction with dichlone residues. It was found in a tryout with cherries that the respective absorbance maxima were 484, 492 and 672 millimicrons. The use of triethylamine with an absorbance maximum wavelength of 672 millimicrons was less susceptible to interference from extraneous material.

The analysis of dichlone by the use of micro-coulometric gas chromatography was researched in Burke (1962, MRID 05002348). The method is discussed as a rapid pesticide screening procedure. The relative retention ratios of 71 pesticides, one being dichlone as compared with aldrin, are reported. Various cleanup procedures are discussed relative to the crop being sampled. The instrumentation used was a Dohrmann micro-coulometric gas chromatograph equipped with an aluminum column, 1/4 inch outside diameter by 6 feet long, packed with 30/60 mesh acid-washed Chromosorb P coated with 20% Dow-Corning high vacuum silicone grease. Helium was the carrier gas at 120 ml/min. Column temperature was $220^{\circ}$C and the injection block temperature $250^{\circ}$C. The relative retention time of dichlone relative to that of aldrin is 0.59.

For the analysis of dichlone in water, an extraction procedure is discussed in Faust (1965, MRID 05003909) consisting of its steam distillation from an acid aqueous medium, after which chloroform for ultraviolet detection is employed. Specifics of this method are discussed in Newell (1954?, MRID 00001515). This method is adequate for the analysis of dichlone from water samples in the range of 8-250 parts per billion with an average recovery of 86%. One of the negative factors affecting the rate of recovery is that some hydrolysis of the 2,3-dichloro-1,4-naphthoquinone to 2-hydroxy-3-chloro-1,4-naphthoquinone occurs. Accordingly, a 100% recovery is seldom achieved. Solutions of 500 and 700 ppb were run but recoveries dropped to 70%.

Additional submissions, (Patrashku, 1971, MRID 05004240; Mills, 1972, MRID 05004950; and Kovacs, 1966, MRID 05003005) discuss a Russian colorimetric method which has very little practical applicability in the USA because of the suggested Russian instrumentation. Two submissions contain practical cleanup procedures that could have been used in the analysis and identification of dichlone residues in agricultural crops. However, the availability of recently developed, advanced and more sensitive methods renders these two procedures obsolete.

## RESIDUE DATA

Field residue data for dichlone reflects the registered use in regard to dosage rate, mode of application, number and timing of treatments, formulations used and geographical areas represented. No metabolism data regarding the fate of dichlone residues in or on agricultural crops were submitted. Accordingly, there is no way of knowing whether or not dichlone _per se_ is the final degradation residue to be determined. However, for the sake of evaluating the residue data submitted, it has to be assumed that dichlone _per se_ is the final residue to be measured.

The analytical method used to generate the residue data involves the stripping of the agricultural crop with benzene, filtering of the extract and concentrating to a smaller volume. An aliquot of the extract is mixed with aqueous dimethylamine for color development with possible dichlone residues. The intensity of the color is then measured on a Beckman DU spectrophotometer. This method was tried out on pole beans, cherries, plums, prunes and strawberries. Samples were fortified over a range from 0.13 ppm to 1.79 ppm. Recoveries ranged from 83%-109%, averaging 91%. This method is deemed adequate for the purpose of collecting residue data.

Residues in or on Apples

No storage stability study of dichlone residues on agricultural crops was submitted. The dichlone residue data at hand do not provide a history of the analyzed samples concerning the dates of collection, whether the samples were kept frozen or when the analyses were performed.

The directions for use on apples call for delayed dormant and for foliar applications up to one day prior to harvest. Two kinds of applications are offered, i.e., single or multiple dust applications at a maximum rate of 1.5 lb. a.i./per acre, (1 day PHI indicated); and single or multiple spray applications at a maximum rate of 4 lb. a.i./acre/application (1 day PHI indicated). Some rates of application are expressed in terms of pounds of a.i./100 gallons of water applied to the point of runoff; however, the maximum amount applied per acre is not indicated. The maximum amount of dichlone applied per acre is dependent on the number and size of trees per acre and whether or not the application is made to a dormant tree or a full covered tree. When applied to the point of runoff, the rate of application expressed in this manner should correct for the number and size of trees.

The available residue data (United States Rubber, 1956, MRID 00001510), reflect seven single 1/2 lb. a.i./100 gallon spray applications to apple trees in six different states of USA. (One application reflects a rate of 1 lb. a.i./100 gallons). The interval between spray and harvest varies from zero days to nine days. The maximum dichlone residues on apples resulting from 1/2 lb. a.i./100 gallon is 1.2 ppm at one day, 0.68 ppm at six days, 0.24 ppm at seven days, 0.1 ppm at eight days and 0.00 ppm at nine days (sensitivity of the method 0.2 ppm). The one application of 1 lb. a.i./100 gallons of water reflects residues of 1.07 ppm at zero day and no residues (0.00 ppm) at seven weeks (sensitivity of the method 0.2 ppm). Apple blanks are reported at 0.0 ppm (sensitivity of the method 0.2 ppm).

These residue data are not adequate to support a 3 ppm tolerance for residues in or on apples because: (1) The residue data reported do not reflect the maximum proposed dosage rate. (2) The residue data do not reflect residues resulting from proposed dust applications. (3) The residue data do not reflect residues resulting from registered multiple dust or spray application. (4) The data do not reflect the registered dormant use of apple trees. (5) Although enough geographic areas are represented, not enough data are presented reflecting the same conditions in the same geographic area.

## Residue on Peaches

The directions for use on peaches call for dormant and foliar applications up to seven days before harvest.

Two kinds of applications are offered, i.e., single or multiple dust applications at a maximum rate of 1.5 lb. a.i./per acre (3 and 7 day PHI's indicated) and single or multiple spray applications at a maximum rate of 2.5 lbs. a.i./acre/application (7 day PHI indicated). There are some rates of application which are expressed as pounds of a.i. per 100 gallons of water.

The available residue data for peaches (United States Rubber, 1956, MRID 00001510) reflect seven single 1/2 lb. a.i./100 gallon spray applications to the foliage of peach trees in five different states of the USA. The interval between spray and harvest varies from zero to nine days. The maximum reported residue on peaches is 1.7 ppm in four studies in three different states at one day after the application; 1.4 ppm six days after the application and 0.3 ppm eight and nine days after the application. Crop blanks are reported as 0.0 ppm (sensitivity of the method 0.2 ppm).

These residue data are insufficient for the same reasons as stated in the above section on residues on apples. These data do not support a tolerance of 3 ppm for residues in or on peaches.

## Residues in or on Tomatoes

Residue data reflecting the use of dichlone on tomatoes are presented in Naugatuck Chemical (1955?, MRID 00001534). The directions for use call for foliar applications, applications to the plant bed and transplant dip-applications. The transplant dip-application is a single application at a rate of 0.5 lb. a.i./100 gallons. The plant bed is treated with multiple spray applications at a maximum rate of 0.5 lb./100 gallons not to exceed 1.25 lb. a.i./acre/application. The foliar applications can be made by multiple dust applications at a maximum rate of 0.6 lb. a.i./acre at unspecified frequency, or by multiple spray applications at a maximum rate of 1.25 lb. a.i./acre. Note: do not exceed 1.25 lb. a.i./acre application.

The reported results were obtained by a method practically identical to the one reported in Miller (1965, MRID 05001416) and Lane (1958, MRID 05001408). This method is deemed adequate for the purpose intended.

Dichlone can be used as late as the day of harvest. The residue data reflect five samples, all representing multiple spray application in one single location (State of Connecticut).

No sample history is reported. Two samples reflecting multiple spray applications at a rate of 0.5 lb. a.i./acre show, at day zero, a residue of 0.92 ppm (three applications) and at seven days after the last application, 0.19 ppm (nine applications). One sample representing four spray applications at a rate of 0.75 lb. a.i./acre shows, at day zero, a residue of 1.25 ppm. One sample reflecting spray applications at 1 lb. a.i./acre shows at zero day a residue of 1.43 ppm. One sample reflecting residues resulting from four spray applications at 1-1/2 lbs. a.i./acre shows at day zero a residue of 2.28 ppm. These residue data are not adequate to support a 3 ppm tolerance for residues in or on tomatoes because: (1) The residue data reported do not reflect all maximum registered uses such as dusts, dips and use on seed beds. (2) The data do not reflect residues that result from various uses in different geographic areas.

### Residues on Celery

The directions for use on celery call for multiple foliar dust applications at a maximum rate of 0.75 lb. a.i./acre every 7-10 days. Multiple foliar spray applications at a maximum rate of 0.50 lb. a.i./acre (not to exceed 0.75 lb. a.i./acre/application) are suggested every 5-7 days beginning 7-10 days after plant set.

The residue data at hand (Naugatuck Chemical, 1955?, MRID 00001534) were collected by the same method as that used for the collection of the tomato residue data. This method is deemed adequate for the intended purpose.

The reported residue data are from one spray location in Florida. Fully grown celery was sprayed with dichlone at the rate of 0.25 lb. a.i./acre (1/2 lb. Phygon XL/acre) and was harvested the same day. The celery was topped but not trimmed. Five samples were analyzed and residues were reported to range from 0.2-1.5 ppm (average 0.68 ppm for five values).

The residue data are not adequate to support a 3 ppm tolerance for residues in or on celery because: (1) The residue data reflect half the registered spray-use of 0.5 lb. a.i./acre. (2) The residue data do not reflect the maximum registered dust use of 0.75 a.i./acre/application. (3) Not enough geographic representation of growing areas are represented. (4) The data do not reflect possible residues resulting from applications in the same geographic area. (5) The residue data do not reflect the use of multiple dust applications to celery at a maximum proposed application rate.

### Residues on Beans

The directions for foliar treatment of beans proposed multiple dust applications at a maximum rate of 1.11 lb. a.i./acre every seven days beginning at pre-bloom, but not within seven days of harvest. Foliar treatment of beans by means of a spray at a maximum registered rate of 1-1/8 lb. a.i./150 gallons of water/acre every seven days for five applications, beginning just before bloom, is an alternate registered use. Do not apply within seven days of harvest.

The analytical method used to determine the residues was the same as that used previously for apples and peaches. The lower limit of sensitivity claimed is 0.2 ppm. The recoveries at fortification levels of 0.13 ppm to 0.64 ppm range from 90%-109%. This method is deemed appropriate for the purpose intended.

The reported data (United States Rubber Company, 19??, MRID 00001529)reflect residue studies on pole beans and string beans in three locations in the State of Washington. Residue data on green beans were all obtained after single applications of dust at a maximum rate of 0.9 lb. a.i./acre. No data were presented on spray-treatments. Eight samples from three locations were analyzed. Seven consisted of "pole" beans and one of string beans. Maximum residues reported were 0.4 ppm in "pole" beans harvested five days after treatment with 0.9 lb. dichlone per acre. All other samples, representing rates of 0.6-0.9 lb. a.i./acre and preharvest intervals 9-21 days, showed residues of 0.0-0.1 ppm (sensitivity of method 0.2 ppm). All blanks were reported as 0.0 ppm (sensitivity of method 0.2 ppm). The reported residue data are not adequate to support a 3 ppm tolerance of residues in or on beans because: (1) The residue data do not reflect the maximum registered use of 1-1/8 lb. a.i./acre. (2) The residue data do not reflect multiple dust applications. (3) The residue data do not reflect the use of multiple spray applications at the maximum registered rate. (4) Not enough geographic areas were represented. (5) Not enough data are presented reflecting uses in the same geographic area at a maximum registered application rate.

## Residues in or on Cherries

The directions for use on cherries propose a single delayed dormant application at the maximum application rate of 1.2 lb. dichlone dust/acre. Multiple foliar dust applications are proposed at a maximum application rate of 1.5 lb./acre. A preharvest interval of three days is indicated. Multiple foliar spray applications are proposed at maximum application rate of 0.50 lb. a.i./100 gallons, not to exceed 5 lb.a.i./acre/application.

Data are reported (United States Rubber Company, 19??, MRID 00001529) on residues from six samples of cherries from three states (a total of five locations). All were sprayed (apparently single applications) at 0.25 lb. a.i. 100 gallons. Maximum residue found was 0.4 ppm on a sample harvested seven days after treatment. All other samples showed residues of 0.0 (sensitivity of method 0.2 ppm) -0.2 ppm,representing pre-harvest intervals of 0, 5 and 7 days. Recoveries from knowns at 0.45-0.90 ppm were 83-106%; all blanks reported as 0.0 ppm.

The reported residue data are not adequate to support a 3 ppm tolerance for residues in or on cherries because: (1) The residue data do not reflect the maximum registered use of 0.5 lb. a.i./100 gallon. (2) The residue data do not reflect the use of multiple dust and multiple spray applications at the maximum registered rate. (3) Not enough residue data were reported resulting from the maximum registered use at various days after the application, establishing a residue decline pattern.

## Residue in or on Plums and Fresh Prunes.

The directions for use on plums reflect a single delayed dormant dust application at the maximum rate of 1.2 lb. a.i./acre. The directions for foliar treatment indicate multiple dust applications at a maximum rate of 1.5 lb. dichlone/acre (three-day PHI indicated). Also, foliar spray applications are suggested at a maximum rate of 0.375 lb./100 gallons, not to exceed 1.25 lb. a.i./acre. A three-day PHI is indicated.

The directions for use on prunes suggest a foliar multiple dust application at a maximum rate of 1.5 lb. a.i./acre (a three-day PHI is indicated). In addition, foliar multiple spray applications are registered at a maximum rate of 0.375 lb. a.i./100 gallons of water, not to exceed 1.25 lb. a.i./acre. A multiple spray application is suggested at a maximum rate of 0.25 lb. a.i./acre with a three-day preharvest interval.

Data are reported (United States Rubber Company, 19??, MRID 00001529) on residues on three samples of plums and two samples of prunes (fresh) from four states. All received single applications of sprays at 0.25 lb. a.i./100 gallons. All samples were harvested seven days after spraying. The maximum residue was 0.6 ppm on a sample of plums from California; residues on all other samples were 0.0 (sensitivity of method 0.2 ppm)-0.1 ppm. Recoveries using samples fortified at 0.63 and 0.90 ppm were 86%-100%. All blanks were reported as 0.0 ppm (sensitivity of method 0.2 ppm).

The reported residue data are not adequate to support a 3 ppm tolerance for residues in or on plums and fresh prunes because: (1) The residue data do not reflect the maximum registered spray application a rate of 0.375 lb. a.i./100 gallons. (2) The residue data do not reflect the use of multiple dust and multiple spray applications at the maximum registered application rate. (3) No data were reported at various times, starting at zero day, which would permit the establishment of a residue decline pattern. (4) No residue data were submitted reflecting the delayed dormant use. Generally, not enough data is reported to justify the maximum registered uses for plums and fresh prunes.

### Residues in or on Strawberries

The directions for use on strawberries suggest a multiple foliar spray application at the maximum registered rate of 0.375 lb. a.i./200 gallon/acre every 10-14 days. Do not apply within three days of harvest.

The residue data reported for strawberries (United States Rubber Company,19??, MRID 00001529) reflect the use of dichlone on seven samples of strawberries from five states. All received single sprays at 0.375-0.5 lb. a.i./acre. The harvest of the samples was 3-19 days after spraying. Of two samples from different locations receiving 0.5 lb. a.i./acre harvested three days after spraying, a maximum residue of 10.5 ppm was reported. Of two samples from two other locations receiving 0.375-0.5 lb. a.i./acre and taken seven days after spraying, the maximum residue was 0.88 ppm. Other samples taken at 6-19 days after spraying had residues of 0.0 (sensitivity of method 0.2 ppm)-0.1 ppm. Recoveries using samples fortified at 9 ppm were 96-98%; at 1.8 ppm, 86% and at 0.43-0.90 ppm, 92-93%. All blanks were reported as 0.0 ppm (sensitivity of method 0.2 ppm).

The reported residue data are not adequate to support a 15 ppm tolerance for residues in or on strawberries because: (1) The residue data do not reflect a residue decline pattern justifying the 15 ppm tolerance. (2) Overall, not enough is reported to reflect the level of residues that may result from the maximum registered use. (3) No sample history is reported indicating the date of analysis as compared to the time of harvest. (4) No sample storage report was submitted.

### Residues in Meat and Milk

Consideration is given to the possible feeding of treated crops and by-products to cattle, horses, pigs, and other farm animals. It is a well-known agricultural practice that apple pomace (wet or dry) is fed to cattle at ca. 1/3 the daily diet. Tomato pulp (dried) is fed to beef and dairy animals at 10-25% of the daily diet; to pigs and horses at 10% of the diet and to finishing lambs at 15-25% of the diet. Bean vines, forage and hay can be fed to beef cattle at up to 20% of the diet and to dairy cows at up to 37% of the diet. No residue studies were reported for the indicated commodities including cover crops in fruit orchards which may be grazed.

These residue studies are essential in order to determine the extent to which dichlone residues are fed to food-animals. If these commodities containing residues are fed to food-animals, then feeding studies with ruminants and nonruminants should be performed at several dosage levels; including exaggerated dosages, preferably threefold and tenfold to determine whether or not residues will transfer to meat and milk. No feeding study with ruminants and nonruminants have been reported.

## REGULATORY INCIDENTS

No report was made on any regulatory action taken by FDA in regard to the registered uses of dichlone.

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# Chapter VII

## Ecological Effects Chapter

DISCIPLINARY REVIEW

Ecological Effects Profile
Ecological Effects Hazard Assessment
Data Gaps
Required Labeling

### Ecological Effects Profile

A limited amount of information is available on the effects of dichlone on birds, fish, aquatic invertebrates, aquatic plants, amphibians, and beneficial invertebrates.

Subacute 8-day avian dietary studies on three species of upland game birds-bobwhite quail (Colinus virginianus), Japanese quail (Coturnix c. japonica) and ring-necked pheasant (Phasianus colchicus) - indicate technical dichlone is practically nontoxic to this group of birds. The values range from >4640 to >5000 ppm. An eight day dietary study on mallard ducks resulted in an $LC_{50}$ >5000 ppm indicating technical dichlone also is practically nontoxic to waterfowl.

Acute 96-hour $LC_{50}$'s are available on both coldwater and warmwater fish. Rainbow trout (Salmo gairdneri) and bluegill sunfish ( Lepomis macrochirus had respective LC50 values of .034 ppm and .041 ppm. These values are sufficient to characterize technical dichlone as being very highly toxic to cold and warmwater fish. Additional acute studies on carp (Cyprinus carpio )have confirmed that technical dichlone is very highly toxic to warmwater fish.

Five species of freshwater aquatic invertebrates - including daphnids (Daphnia magna) and amphipods (Gammarus fasciatus) have been tested against technical dichlone. The subacute LC50's range from 14 ppb to 45 ppb. These data indicate technical dichlone is very highly toxic to freshwater aquatic invertebrates.

For algae the no-effect concentration is dependent upon the species. Studies have shown a no-effect concentration ranging from 75 ppb (0.253 uM/1) to 32 ppm (115.6 uM/1).

Aquatic macrophytes, emerged and submerged, apparently are quite tolerant of dichlone. Ten species from various families and divisions were unaffected at 12 ppm dichlone.

For terrestrial plants, the no-effect levels range from 3 lb/100 gal. diluant for tobacco (senescence retardant), to 59 mg/tomato seedling, to 2 oz./cwt of sugarbeet seed and 16 ppm for cucumber seed.

During seed treatment of legumes, the nitogen fixing symbiont, Rhizobium , may be affected by a 1 to 2 oz./cwt treatment, however, the legume growth and yield will not be affected.

One study on an amphibian, the South African clawed toad (*Xenopus laevis* ), examined the effects of dichlone on developing embryos. In this short-term teratology study, dichlone produced effects at concentrations greater than 75 ppb and 50% mortality within one day of exposure between 125 ppb and 150 ppb. These data suggest dichlone is very highly toxic to early life stages of amphibians.

One scientifically sound beneficial insect study was conducted on a wettable powder formulation containing dichlone. Phygon Xl was tested against the honey bee (*Apis mellifera*). There is sufficient information to characterize the product as moderately toxic to bees when ingested and relatively nontoxic to bees exposed to direct application or dried residue. When bees were exposed to Phygon Xl in orchards at 0.5 lb. of formulation/100 gals, the product was not toxic or repellent.

## Ecological Effects Hazard Assessment

The Ecological Effects Branch anticipates that some of dichlone's use patterns are likely to contaminate aquatic sites adjacent to treated fields as well as vegetation in and around the target site. Aquatic organisms appear to be sensitive to dichlone. Although environmental fate data are not available, it is evident that the direct application of the 5% product at 5 gallons per 1,000,000 gallons of water will produce a concentration of 0.25 ppm. This is about 32 times the acute $LC_{50}$ (0.034 ppm) for rainbow trout. This constitutes a hazard to fish, indicating the need for the following label statement, "Consult your State fish and game agency before applying this product. Fish may be killed at label application rates". The Agency will address other aquatic concerns upon receipt of acceptable environmental fate data.

## Data Gaps

All registrants of dichlone products must fulfill the data requirements as summarized on pages 20 through 22. A full description of the data requirements can be found in the Proposed Guidelines for the Registration of pesticides in the United States, 43 FR 29696, July 10, 1978 and 45 FR 72948, November 3, 1980.

## Ecological Effects Labeling Requirements

All manufacturing-use dichlone product labels must include the following warning:

"This pesticide is toxic to fish and other aquatic organisms. Do not discharge into lakes, ponds, or public water unless in accordance with NPDES permit. For guidance, contact your Regional Office of the EPA."

All labels for formulated dichlone products intented for use as fungicides and as algaecides in swimming pools must include the following warning:

> "This pesticide is toxic to fish and other aquatic organisms. Do not contaminate water by cleaning of equipment or disposal of wastes."

All labels for formulated dichlone products intended for use as algaecides in lakes and ponds must include the following warning:

> "This pesticide is toxic to fish and other aquatic organisms. Fish may be killed at the label application rates. Do not apply to fish bearing waters."

All labels for food crop and ornamental uses must bear a statement similar to:

> "This pesticide is toxic to fish."

Additional labeling will be deferred until the required data has been received and evaluated.

## TOPICAL DISCUSSIONS

Corresponding to each of the Topical Discussions listed below is the number of the section(s) in the 'Proposed Guidelines' (43 FR 29696, July, 10, 1978 and 45 FR 72948, November 3, 1980) which explain(s) the data that the Agency will utilize to adequately assess dichlone's Ecological Effects. Where no section number is listed, a minimum requirement has not been set for such information.

| Category of Test | Guideline Number |
|---|---|
| Effects on Birds | 163.71-1,2,4 |
| Effects on Mammals | 163.71-3 |
| Effects on Freshwater Fish | 163.72-1 |
| Effects on Aquatic Invertebrates | 163.72-2 |
| Effects on Terrestrial Macrophytes | 163.122-1 |
| Effects on Algae | 163.122-2 |
| Effects on Aquatic Macrophytes | 163.122-2 |
| Nitrogent Fixation Potential | 163.125-3 |
| Effects on Amphibians | |
| Effects on Beneficial Invertebrates | |

The following are the categories of toxicity used in the topical discussions.

## Mammalian

Acute Oral (mg/Kg)

| | |
|---|---|
| <10 | very highly toxic |
| 10-50 | highly toxic |
| 51-500 | moderately toxic |
| 501-2000 | slightly toxic |
| >2000 | practically nontoxic |

## Avian

Acute Oral (mg/Kg)

| | |
|---|---|
| <10 | very highly toxic |
| 10-50 | highly toxic |
| 51-500 | moderately toxic |
| 501-2000 | slightly toxic |
| >2000 | practically nontoxic |

Dietary (ppm)

| | |
|---|---|
| <50 | very highly toxic |
| 50-500 | highly toxic |
| 501-1000 | moderately toxic |
| 1001-5000 | slightly toxic |
| >5000 | practically nontoxic |

## Aquatic Organisms

ppm

| | |
|---|---|
| <0.1 | very highly toxic |
| 0.1-1 | highly toxic |
| >1-10 | moderately toxic |
| >10-100 | slightly toxic |
| >100 | practically nontoxic |

*Category terminology taken from: Brooks, H.L. et al. (1973). Insecticides, Cooperative Extension Service, Kansas State University, Manhattan, Kansas.

## AVIAN SINGLE DOSE ORAL $LD_{50}$ (163.71-1)

Data on the single-dose oral $LD_{50}$ are required to support the registration of manufacturing-use dichlone and all formulated dichlone products when intended for outdoor use. Technical dichlone is the preferred product to be tested. The species tested shall be the same as one of the two species selected for the avian dietary $LC_{50}$ in Section 163.71-2.

There were no studies submitted to the Agency dealing with avian single-dose oral $LD_{50}$. This constitutes a data gap.

## AVIAN DIETARY $LC_{50}$ (163.71-2)

A determination of the subacute dietary $LC_{50}$ is required to support the registration of all manufacturing-use dichlone and all formulated dichlone products when they are intended for outdoor use. Technical dichlone is the preferred test material. The mallard duck, bobwhite quail or ring necked pheasant are the preferred test species.

The following two studies reporting four test results were reviewed and found to be adequate for registration.

| Species | Formulation | $LC_{50}$ (ppm) | Reference |
|---|---|---|---|
| Mallard | 95% | >5000 | Hill, 1975 |
| Ring-Necked Pheasant | 95% | >5000 | " " |
| Bobwhite Quail | 95% | >5000 | " " |
| Bobwhite Quail | 98.4% | >4640 | Fink, 1973, MRID 00001549 |

There is sufficient information to characterize dichlone as slightly to practically nontoxic to upland game birds and waterfowl.

## AVIAN REPRODUCTION (163.71-4)

A reproduction study is required to support the registration of a formulated dichlone product if any of the following conditions exists: 1) dichlone is persistent in the environment, 2) dichlone is stored or accumulated in plant or animal tissue, and 3) the dichlone product is intended for use where birds may be subjected to repeated or continued exposure. The test material will be technical dichlone. The bobwhite quail and mallard duck are the preferred species.

No data on avian reproduction have been submitted to the Agency. This is a required study because the use of dichlone on agricultural crops would subject birds to repeated exposure.

## MAMMALIAN ACUTE TOXICITY (163.71-3)

These data are not needed for dichlone because the data on laboratory animals reviewed in the Toxicology Chapter are generally sufficient for an estimate of toxicity to wild mammals. Based on the data in dichlone's oral toxicology review, there do not appear to be any unusual hazards to wild mammals.

## FISH ACUTE TOXICITY (163.72-1)

A determination of the 96 hour $LC_{50}$ is required to support the registration of manufacturing-use dichlone and of each formulated dichlone product. The test material required is technical dichlone. In addition, a formulated product must be tested if its intended use is direct introduction into the aquatic environment. The rainbow trout and bluegill sunfish are the preferred species.

Three studies were reviewed and the data are presented below:

| Species | Formulation | $LC_{50}$ (ppm) | Reference |
|---|---|---|---|
| Rainbow trout | 97% | 0.034 | McCann, 1976a |
| Bluegill sunfish | 97% | 0.041 | McCann, 1976b |
| Fathead minnow | 100% | 0.150 | Maloney and Palmer, 1956, MRID 05003523 |

There are significant data to characterize dichlone as very highly toxic to both coldwater and warmwater fishes. There were no tests using the ready-to-use, wettable powder, or flowable concentrate formulations. This constitutes a data gap for these formulations.

## ACUTE TOXICITY TO AQUATIC INVERTEBRATES (163.72-2)

A determination of the $EC_{50}$ or $LC_{50}$ for an aquatic invertebrate species is required to support the registration of manufacturing-use dichlone and of each formulated dichlone product. The test material will be the technical material. In addition, a formulated product will be tested if its intended use is direct introduction into the aquatic environment. Immature invertebrates (daphnids, amphipods, stoneflies, or mayflies) should be used whenever possible.

Three studies were reviewed, and the data follows in Table 6 on the following page.

## Table 6

### Effects of Dichlone on Aquatic Invertebrates

| Species | Formulation | $LC_{50}$ (ppm) | Reference |
|---|---|---|---|
| *Daphnia magna* | Technical | 0.025 (48 hr.) | Sanders (1970)<br>MRID 05001497 |
| *Cypridopsis vidua* | Technical | 0.12 | " |
| *Gammarus fasciatus* | Technical | 0.24 | " |
| *Asellus brevicaudus* | Technical | 0.20 | " |
| *Palaemonetes kadiakensis* | Technical | 0.45 | " |
| *Daphnia magna* | Technical | 0.014 (26 hr.) | Crosby and Tucker,<br>1966, MRID 05001465 |
| *Daphnia magna* | Unknown | 0.026 (26 hr.) | Frear and Boyd,<br>1967, MRID 00002875 |

These tests do not conform to the protocol as stated in the EPA 1978 guidelines. However, collectively, using the data above, there is sufficient information to characterize dichlone as highly toxic to aquatic invertebrates. Consequently, no further acute aquatic invertebrate toxicity studies are required on the technical. No tests were conducted using the formulations that are used in the aquatic environment. Therefore, to complete a hazard evaluation, the ready-to-use, flowable concentrate, and wettable powder formulations must be tested.

### TERRESTRIAL MACROPHYTES (163.122-1)

As a wettable powder seed treatment, 2 oz. ai/cwt of seed has no effect on peas, waxbeans, sugar beets, or cucumbers. As a foliar spray, 3 lb. ai/100 gal. water or greater than 0.56 kg. ai/ha did not effect tobacco except to retard senescence. A half a pound ai/100 gal. water does not affect either tomates or potatoes.

| Species | Formulation | No Effect or EC10 Level | Reference |
|---|---|---|---|
| Tobacco | ai | >3 lb/100 gal | Rich and Taylor (1957) MRID 05001576 |
| | wp (50%) | >1.12 kg/ha §retards chlorophyll senescence† | Walker (1966) MRID 05001635 |
| Tomato | ai | 59 mg/seedling (0.125%) | Jacks (1951) MRID 05001433 |
| | 50% (liquid) | 0.5 lb ai/100 gal | Bilbruch and Rich (1961) MRID 05003839 |
| Potato | 50% (Liquid) | 0.5 lb ai/100 gal | Bilbruch and Rich (1961) MRID 05003839 |
| Sugar Beets | 50% ai | 2 oz ai/100 cwt seed | Wheatley and Johnson (1962) MRID 05001489 |
| Oats | (antagonism with DCPA but not with 2,4-D) | | Nash and Harris (1973) MRID 05001493 |
| Cucumber | ai | >16ppm | |
| | ai | >4 ppm + <0.13 ppm 2,4-D (synergism) | Nash and Harris (1973) MRID 05001493 |
| | wp (50%) | >2 oz ai/cwt seed | deZeeuw et al. (1959) MRID 05001580 |
| Peas | wp (50%) | >2 oz ai/cwt seed | deZeeuw et al. (1959) MRID 05001580 |
| Beans, Wax | wp (50%) | >2 oz ai/cwt seed | deZeeuw et al. (1959) MRID 05001500 |

There is an antagonistic effect with DCPA and a synergistic effect with 2,4-D while neither dichlone nor DCPA or 2,4-D exhibited any effect (up to 0.13 ppm with 2,4-D)

## EFFECT OF DICHLONE ON ALGAE (163.122-2)

The no observed effect level of dichlone on algae, when introduced as the technical material, varies from species to species. As shown below, the values range from .075 ppm to 32 ppm.

| Species | No Effect Level | Reference |
|---|---|---|
| *Anacystis nidulans* | 0.075 ppm<br>(in light) | Whitton (1966) MRID<br>05002615 |
| *Calothrix braunii* | 2.0 ppm | Maloney and Palmer, 1956,<br>MRID 05003523 |
| *Cylindrospermum licheniforme* | 4.0 ppm | " |
| *Microcystis aeruginosa* | 0.25 ppm | " |
| *Nostoc muscorum* | 0.25 ppm | " |
| *Phormidium tenue* | 2.0 ppm | " |
| *Plectonema nostocorum* | 0.25 ppm | " |
| *Symploca erecta* | 1.0 ppm | " |
| *Ankistrodesmus falcatus* | 32.0 ppm | " |
| *A. falcatus acicularis* | 4.0 ppm | " |
| *Chlamydomonas communis* | 2.0 ppm | " |
| *C. paradoxa* | 1.0 ppm | " |
| *Chlorella variegata* | 4.0 ppm | " |
| *Chlorococcum botryoides* | 32.0 ppm | " |
| *C. humicola* | 8.0 ppm | " |
| *Coccomyxa simplex* | 8.0 ppm | " |
| *Coelastrum proboscideum* | 16.0 ppm | " |
| *Gloeocystis gravillei* | 2.0 ppm | " |
| *Mesotaenium caldariorum* | 4.0 ppm | " |
| *Oocystis lacustris* | 16.0 ppm | " |
| *O. marsonii* | 32.0 ppm | " |
| *Scendesmus basilensis* | 32.0 ppm | " |
| *S. obliquus* | 32.0 ppm | " |
| *Sphaerella lacustris* | 0.5 ppm | " |
| *Stigeoclonium nanum* | 4.0 ppm | " |
| *Achnanthes linearis* #1 | 1.0 ppm | " |
| *Achnanthes linearis* #2 | 1.0 ppm | " |
| *Gomphonema parvulum* | 1.0 ppm | " |
| *Nitzschia palea* #1 | 1.0 ppm | " |
| *Nitzschia Palea* #2 | 0.5 ppm | " |
| *Nitzschia palea* #3 | 0.5 ppm | " |

In a laboratory study using *Chlorella pyrenoidosa*, dichlone ($3 \times 10^{-3}$M) exhibited a short term growth reduction of 56% while chlorophyll content and oxygen evolution was reduced 100% (Zweig et al., 1968, MRID 05001627).

In another laboratory study, Zweig et al. (1972, MRID 05001597) showed that the $EC_{50}$ for *Chlorella* carbon dioxide fixation was 1.05 uM.

## EFFECT OF DICHLONE ON AQUATIC MACROPHYTES (163.122-2)

Technical dichlone had no apparent phytotoxic effect on 10 aquatic macrophytes during an outdoor pond test. The no-effect level was found to be greater than 12 ppm. The common and species names are listed below (Audia and Preston, 1965, MRID 05002173).

| | |
|---|---|
| Soft rush | *Juncus effusus* |
| Swamp potato | *Sagittaria sinensis* |
| Water Purslane | *Ludwigia palustris* |
| Pepperwort | *Marsilea quadrifolia* |
| Water Fern | *Azolla caroliniana* |
| Salvinia | *Salvinia rotundifolia* |
| Floating Fern | *Ceratopteris thalictroides* |
| Water Hyacinth | *Eichornia crassipes* |
| Water Lettuce | *Pistia stratiotes* |

## NITROGEN FIXATION POTENTIAL (162.125-3)

Because soybeans and other legumes, to be economicaly feasable in their growth and production, require a bacteria symbiont (*Rhizobium spp.*) to fix atmospheric nitrogen, the sensitivity of this symbiont to dichlone will be covered in this section.

In pure culture, *Rhizobium* species show varying sensitivities according to the resistance or sensitivity of the strain. However, 30 ppm is a minimal value that was determined on seven species.

As a seed treatment at the time of innoculation with *Rhizobium*, dichlone at 1 or 2 oz ai/cwt of legume seed is the no effect level for the growth and yield of the plant even though the *Rhizobium* may be physiologically affected and slow to infect.

| + or - symbiosis with legume | No effect Level | Reference |
|---|---|---|
| +(Subterranean Clover) | 4 oz/cwt<br>(50% powder) | Williams et al. (1960)<br>MRID 05001377 |
| -(cowpea *Rhizobium* ) | 50 ppm (sensitive)<br>400 ppm (resistant) | Odeyemi (1976) MRID 05001655 |
| +( *R leguminosarum* ) | 2 oz/cwt<br>(50% powder) | Ruhloff and Burton (1951)<br>MRID 05001773 |
| -(7 species of *Rhizobium* ) | 30 ppm (w/v) | Afifi et al. (1969)<br>MRID 05002504 |

## EFFECT OF DICHLONE ON AMPHIBIANS

A teratology study was conducted on the embryo of the South African clawed toad (*Xenopus laevis*). When 0.15 ppm of technical dichlone was applied to the embryos, they completely disintegrated within one day (Anderson and Prahlad,1976, MRID 05005290).

There is sufficient information to characterize the toxicity of dichlone as very highly toxic to the early life stage of amphibians.

## EFFECT OF DICHLONE ON BENEFICIAL INVERTEBRATES

One study showed that 0.5 lb/100 gal. water of Phygon XL was not toxic to honey bees (*Apis mellifera*) exposed to direct application or dried residues. However, the material was moderately toxic in a feeding study. Dichlone was also found not to be repellent to bees in field tests (King, 1959, MRID 05001322).

There is sufficient information to characterize dichlone as low in toxicity to honey bees, except when ingested.

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# OFFICE OF PESTICIDE PROGRAMS

# PESTICIDE DOCUMENT MANAGEMENT SYSTEM

# CASE BIBLIOGRAPHY

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1. Content of Bibliography. This bibliography contains citations of all the studies reviewed by EPA in arriving at the positions and conclusions stated elsewhere in this standard. The bibliography is divided into 2 sections: (1) citations that contributed information useful to the review of the chemical and considered to be part of the data base supporting registrations under the standard, and (2) citations examined and judged to be inappropriate for use in developing the standard. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions, and the published technical literature.

2. Units of Entry. The unit of entry in this bibliogrpahy is called a "study". In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to a published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of reivew, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. Identification of Entries. The entries in this bibliography are sorted by author, date of the document, and title. Each entry bears, to the left of the citation proper, and eight-digit numeric identifier. This number is unique to the citations, and should be called the "Master Record Identifier", "MRID". It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted data; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. This is also to be used whenever a specific reference is needed.

4. Form of the Entry. In addition to the Master Record Identifier (MRID), each entry consists of a bibliographic citation containing standard elements followed, in the case of materials submitted to EPA, by a description of the earliest known submission. The bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs. Some explanatory notes of specific elements follow:

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b. Document Date. When the data appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

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    (1) Submission Date. Immediately following the word "received" appears the date of the earliest known submission.

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    (3) Submitter. The third element is the submitter, following the phrase "submitted by". When authorship is defaulted to the submitter, this element is omitted.

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